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Central Washington Hospital

September 14, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: CMS-1501-P Proposed changes to Hospital OPPS 2006
Drug Administration Proposed Changes for 2006

Dear Dr. McClellan,

I would like to express concern regarding the proposed G-code usage for drug administration. I believe that the CPT codes already assigned for infusion, IV, IM/SC, IM Antibiotic injections etc. are self explanatory and should not require an additional code to signify sequential administrations. The addition of modifiers to necessitate additional payment confirms the intentioned appended charges to the claim. It would seem that the proposed changes would make this whole reporting process cumbersome and almost impossible to report it accurately due to the need for a manual capturing system. The groupers used by most OPPS facilities enable a timely self-check system prior to bill drop. CMS won't be able to track services provided to Observation patients with such a difficult billing requirement. We know that APC payment for G0244 only impacts hospital payment for 3 diagnosis categories. (CHF, Asthma, Chest Pain). The cases requiring multiple drug administrations are mostly related to management of abdominal pain, back pain, and many other common problems not associated with the covered diagnosis codes. Please reconsider the change from CPT to G-codes for the difficult task of applying drug administration charges.

Sincerely,

Kathy Poltz

Kathy Poltz RN
Reimbursement Nurse Auditor
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Cc. Warren Arnold, Dir. Reimbursement

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September 13, 2005

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ALLINA
Hospitals & Clinics

Re: File Code CMS – 1501-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Program System and Calendar Year 2006 Payment Rates; Proposed Rule, July 25, 2005, Federal Register.

Dear Dr. McClellan;

I appreciate the opportunity to comment on the proposed rule concerning the hospital outpatient prospective payment system on behalf of Allina Hospitals & Clinics. Allina Hospitals & Clinics is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, medical transportation, pharmacy and hospice services. Allina serves communities throughout Minnesota and western Wisconsin.

The complexity of the OPPS program continues to challenge us. We encourage CMS's efforts to ease regulatory complexity, with continued attention to our goal of providing high quality patient care and long-term financial viability for our communities. We appreciate the options CMS presented in this rule and your openness to listen and understand real world application of the proposals. Please review and consider our comments as you write the final rule.

General Comments

The purpose of commenting on rules and regulations is to help CMS identify issues and errors in your proposals. The short timeline between the comment date and the effective date of the final rule does not allow adequate time for system/software changes. We encourage you to change your proposed rule publication date to July 1, with the final rule to be published on October 1. We would appreciate one additional month to plan and implement the final OPPS rule. This is especially important with the elimination of the HCPCS grace period and requires that all of our systems and our vendor systems are all up to date within the 2 month period. We understand that this timeline would create issue with the inpatient rule; however the inpatient rule is not nearly as complex to administer. We would support the publication of the proposed outpatient rule prior to the publication of the final inpatient rule.

APC Relative Weights
The major volatility in APC weights continues to be of concern. Since the billing data is used to recalibrate the weights, we assume that the CMS policy developers are collaborating intensely with the billing process and systems staff. We continue to have significant hardship in implementing policy that seems to have little consideration for what it takes to bill accurately. We expect that CMS will continue to assess the complexity of implementation in operations and in billing processes before regulatory policy is promulgated. We feel very strongly that CMS needs to do a better job of assessing implementation implications before regulations are established. The number of billing errors could be significantly reduced if there was much greater integration of key process owners before providers are faced with implementation. If CMS could do better in developing regulation that can be easily implemented and supported by CMS/Contractor systems we could all probably reduce the number of resources utilized in addressing billing errors.

Outlier Payments
Outlier payments are important to our hospitals as a means of mitigating losses when treating high end cases. We urge CMS to continue with this payment structure. However, we have concerns that decreasing the outlier pool and increasing the threshold may encourage more packaging. Formula changes make it difficult to qualify for outlier payments. Hospitals may want to package in order to develop higher procedure charges and CMS would lose data on specific charges. The yearly changes in the outlier structure are interesting to us. Perhaps you could verify that increasing the threshold will insure that the outlier pool more accurately reflects the need for outlier payments before making additional changes.

Stereotactic Radiosurgery
We support discontinuing the G codes, however, we do not agree with the potential to combine treatment codes with planning codes. Even though these two services may be provided on the same day, they are very different procedures requiring different skills and resources. This logic does not follow the charge process established for other radiation treatment and planning codes which are always charged separately.

Other New Technology Services
We have significant concern about the reimbursement reduction proposed for MEG APC values. We understand that the APC Advisory Panel recommended that due to insufficient data, the current values be maintained for 2006. We heartily support this recommendation and hope you reconsider this very large proposed payment reduction.

Pass Throughs
We wonder why CMS needs to keep the set aside for pass throughs when there are no qualifiers for this year. Are we correct in our assumption that you are already aware of potential new pass through approvals you need the hold dollars for? If not, we would like to see the dollars released and used to further modify the APC weights or to decrease the outlier threshold.

Non Pass Throughs

Chronic Wound Treatment

We have concerns regarding the proposed reductions in payment for two products, Apligraf and Dermagraft, living human tissue substitutes used to treat chronic wounds. Based on clinical evidence, both are FDA PMA approved and in use for more than five years. These products have improved the quality of life of thousands of Medicare beneficiaries who suffer from chronic ulcers. As demonstrated in pivotal trials, many Medicare patients would have likely undergone amputations without the benefits of these products.

Since 2002, both Dermagraft and Apligraf were paid as biologics under the transitional pass through program. Additionally, both products have been paid for as sole-source biologics in 2004 and 2005 since the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In the 2006 proposed rule, CMS proposes to reimburse specified covered outpatient drugs at average sales price [ASP] + 6 % for the acquisition cost of the drug.

For some reason however, in the proposed rule both Dermagraft and Apligraf were incorrectly paid based on 2004 claims data instead of payment based on ASP. Because of the claims data calculation, both products experienced a significant decrease in payment which is unacceptable for purchasing hospitals:

Medicare Hospital Outpatient

	2005 – Actual	**2006 – Proposed**
Apligraf [C 1305]	$ 1,130.88	**$ 766.84**
Dermagraft [C 9201]	$ 529.54	**$ 368.32**

Apligraf and Dermagraft have been reimbursed in the hospital outpatient setting as covered outpatient drugs and this payment methodology should continue in 2006. Without this, Medicare beneficiary access to these advance treatment options may be jeopardized. We request that the proposed 2006 Medicare hospital outpatient reimbursement for Dermagraft and Apligraf be corrected in the final rule.

Anti Emetics

While we appreciate CMS's attempt to support payment for those specified anti-emetics by exempting them from the $50 threshold, it is operationally impossible for us to establish a separate process for charging these drugs when they are used only in conjunction with chemotherapy. The majority of our surgical outpatients receive these drugs. Could CMS develop an edit to only pay for the anti-emetic when it's connected to a chemo diagnosis?

Pharmacy Overhead Costs

We vehemently oppose the use of 'C' codes for drug handling. This presents an operational nightmare as every drug requires "handling". Every drug would need a handling code. This will create extremely long patient bills and patient confusion in addition to the resources required to be sure the right handling code gets put on the right drug. Other payers do not recognize 'C' codes and this proposal would require that hospitals establish one charging process for Medicare and another charging process for all other payers.

While we appreciate that CMS recognizes the resource utilization in handling drugs, we ask that you do not implement this proposed change but instead complete further assessment along with

analysis of systems implications with such a change. Involve hospitals systems to assist in completing the analysis as we are the end users of such regulatory implications.

Drug Administration
While we support the need for consistency between professional and hospital billing for drug administration, we have big concerns about the short timeframe we could be facing if the final rule is published in early November and we have to implement by December 31, 2005. With the loss of the HCPC's grace period this will be extremely difficult to successfully implement by January 1, 2006. These changes are very significant and the confusion will be great. Not only are there more codes, but different definitions for some of the same services, and new terminology that will require big efforts with education and training, as well as increased focus on documentation. CMS must develop very clear guidance on the use of these codes as soon as possible. We would like to see implementation of this proposed change delayed until the 2nd quarter of 2006.

Observation Services
Thank you for listening to our concerns about the complexity of charging for observation services. We support the proposed coding changes. However, we seek clarification on the process for billing observation when the patient is in over the midnight hour. Would we bill for a total number of observation hours regardless of the date of service or will you address the edit that stops the claim if two observation charges occur on the same claim? It would be very helpful if CMS could develop a good training package for us to use with our physicians. It would be fantastic if physicians could get the same message from all of the facilities they are admitting to observation in.

Inpatient Procedures
We continue to support the Advisory Panel's recommendation to eliminate the Inpatient Only Procedure List and support any movement of procedures off of the list.

Multiple Diagnostic Imaging Procedures
We understand the desire of CMS to reduce costs of imaging. From an operational perspective, the categories make sense as a way to address the issue except in the areas of ultrasound and CT/MRI.

In ultrasound specifically, we have issues with the inclusion of transvaginal ultrasound in the family. This procedure requires the use of a different imaging probe that involves additional preparation work. There a definitely additional resources utilized and we should be reimbursed appropriately rather than face a 50% reduction. We ask that CMS pull transvaginal ultrasound out of the family and continue to pay 100% when appropriate.

In regard to the CT's and MRI's, although the procedures can be set up without additional resources on the front end, there are additional resource needs required post procedure to reconstruct the images and analyze the data. We ask that CMS look closely at the list of CT and MRI procedures and consider a 25% reduction rather than the proposed 50% reduction. Operationally these procedures will require duplication of all aspects of the procedure with the

exception of moving the patient off the table. We feel that a 25% reduction is a more appropriate reflection of the reduced resources required for multiple procedures in the same family.

Beneficiary Co Insurance
We support any reduction in the level of co insurance required for outpatient procedures. Thank you.

Interrupted Procedures
We oppose the proposed reduction of payment for any procedure with a -74 modifier. Discontinuing a procedure after anesthesia is administered occurs only when something is seriously wrong. These patients require just as much and maybe more time and resource as a case that is completed. We ask that you reconsider the reduction in payment for a -74 modified procedure and pay 100% when it occurs.

Allina appreciates the opportunity to provide comments on the Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2006. We hope that CMS will consider our recommendations. If you have any questions, please feel free to contact me at 612-775-9744. We look forward to seeing the final rule.

Sincerely,

Nancy Payne

Nancy Payne, RN, MA
Director of Regulatory Affairs
Allina Hospitals and Clinics

Medical Imaging Contrast Agent Association

125 ORIGINAL

JMASINS

Burley
Kane
Sanow
Hart
Bazell

September 14, 2005

Via Overnight Mail
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1501-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1501-P
Comments to the HOPPS Proposed Rule – Non-Pass Throughs

Dear Dr. McClellan:

The Medical Imaging Contrast Agent Association (MICAA) is pleased to submit comments pertaining to the proposed rule updating the Medicare hospital outpatient prospective payment system ("HOPPS") as set forth in the Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year (CY) 2006 Payment Rates (the "Proposed Rule"), 70 Fed. Reg. 42,674 (July 25, 2005). MICAA is a national non-profit association comprised of developers, suppliers, and manufacturers of medical imaging contrast agent drugs, all of which are administered in the hospital outpatient setting. Medical imaging contrast drugs are increasingly important to accurately diagnose and effectively manage Medicare patients with serious conditions. They enable health care providers to have better information and make more informed treatment decisions.

In brief, our comments are as follows:

- MICAA supports CMS's proposal to recognize the new HCPCS codes for several medical imaging drugs, including low osmolar contrast materials ("LOCM") in the hospital outpatient setting.
- MICAA supports CMS's proposal to pay separately for LOCM.
- MICAA recommends that CMS pay separately for all MR contrast drugs based on ASP data reported.
- MICAA supports the APC Advisory Panel and American College of Radiology's ("ACR's") recommendations to delay for one-year the discount proposed for certain multiple procedures.

- MICAA requests that CMS clarify the coding and payment guidelines for high osmolar contrast material ("HOCM") to permit hospitals to reflect charges and be reimbursed for HOCM products using the recently created HCPCS codes for HOCM and revenue code 636.

- MICAA encourages CMS to continue examining the adequacy of pharmacy handling costs for all medical imaging contrast drugs.

I. Discussion and Recommendations

A. MICAA supports CMS's proposal to recognize the new HCPCS codes for several medical imaging drugs, including LOCM, in the hospital outpatient setting.

MICAA supports CMS's proposal to activate the new HCPCS codes for LOCM (Q9945-9951) that were created in CY 2005 and discontinue the use of the A-codes for LOCM (A4644, A4645, and A4646) in the hospital outpatient setting. We believe this change will promote consistency across sites of services. Such a change will also enable CMS to collect HOPPS claims data on the new Q codes to make future determinations about their packaging status. We request that CMS similarly recognize the new HCPCS codes for other medical imaging contrast agents, including echocontrast drugs. Further, in the event that CMS's HCPCS workgroup replaces the temporary Q codes for contrast materials with permanent ones, we recommend that CMS implement the permanent codes in the hospital outpatient setting as soon as practicable.

B. MICAA supports CMS's proposal to pay separately for LOCM

MICAA supports CMS's proposal to pay separately for LOCM using an ASP-based methodology. We believe that this change appropriately recognizes the cost of these drugs and the fact that they meet CMS's requirements for separate payment (i.e., the 2004 hospital claims data shows that their costs exceed the $50 packaging threshold).

C. MICAA recommends that CMS also pay separately for all MR contrast drugs based on ASP data.

MICAA requests that CMS provide for separate payment of all magnetic resonance ("MR") imaging contrast drugs, including MR imaging drugs covered by Q9953 (Iron-based MR Contrast, per ML), in the HOPPS Final Rule. In the Proposed Rule, CMS states that it did not provide for separate payment for Iron-based MR drugs because it was not able to determine payment rates based on the ASP methodology. We understand that, subsequent to the publication of the Proposed Rule, CMS obtained ASP data showing costs in excess of the $50 threshold for packaging. Based on this data, we recommend that CMS clarify and provide for separate HOPPS payment of all MR agents including Q9953 in 2006.

D. MICAA supports the APC Advisory Panel and ACR's recommendations to delay for one-year the discount proposed for certain multiple imaging procedures.

In keeping with the recommendations of the APC Advisory Panel and ACR, MICAA requests that CMS delay for one-year the discount proposed in the HOPPS Proposed Rule for certain multiple imaging procedures. We understand that for 2006, CMS is proposing implementing its long-standing policy of reducing payment for multiple procedures furnished during the same patient encounter for "eleven (11) families" of imaging procedures. These procedures include, among other things, ultrasound, CT, CTA, MRI, and MRA. As ACR discusses in its comment letter, a copy of which is attached, CMS's reliance on the Medicare Physician Fee Schedule data and methodology may have improperly disregarded the cost efficiencies already captured and accounted for in hospitals' annual cost reports to CMS, which are factored into APC payment rates. We are concerned that applying the discount, as proposed, in the hospital outpatient setting would disadvantage hospitals relative to other imaging facilities because it would unnecessarily apply an additional 50% reduction to already discounted HOPPS payment amounts.

MICAA believes that a more appropriate and accurate measure of costs in the hospital outpatient setting would be using data and methodology internal to the HOPPS/APC process. We believe a one-year delay in implementing the proposed discount will give CMS time to examine this data and further consider the proposed imaging procedure discount.

E. MICAA requests that CMS clarify the coding and payment guidelines for HOCM.

MICAA requests that CMS clarify the coding and payment guidelines for HOCM that will be applicable during calendar year 2006. We support allowing hospitals to bill and be reimbursed for these agents using the recently assigned HCPCS codes (Q9958-Q9964) and revenue code 636. Such a policy is consistent with CMS's proposed treatment of LOCM in the hospital outpatient setting and CMS's proposed treatment of HOCM and LOCM in the physician office/freestanding imaging setting. However, we share the concern voiced by some hospitals that, based on information in an existing CMS program manual, CMS may deny HOPPS claims for HOCM. We note that Section 3631 of CMS's Intermediary Manual provides that "if billing separately, hospitals use revenue code 255" for contrast material other than LOCM. This Manual instruction predates CMS's recent creation of HCPCS codes covering several contrast agents and determination that, based on their costs, some contrast materials should be paid separately. To prevent confusion and the inappropriate denial of claims, we request that CMS specify that hospitals should disregard the program manual instruction and use revenue code 636 and the new Q codes when billing for HOCM. In addition, we request that CMS reimburse hospital outpatient providers for HOCM agents using the ASP methodology.

F. MICAA encourages CMS to continue examining the adequacy of pharmacy handling costs for all medical imaging contrast drugs.

MICAA requests that CMS continue to examine the adequacy of pharmacy handling costs for all drugs, including contrast material such as LOCM and echocontrast agents. We believe that proactive review of this issue is particularly important as CMS transitions to ASP-based payment under HOPPS for separately reimbursable drugs.

* * * *

We would be pleased to discuss any of these issues with CMS in greater detail and will contact the agency to follow-up on these recommendations.

Sincerely,

Jane Majcher
Jane Majcher
Co-Chair
MICAA Health Care Committee

Jay Schafer
Jay Schafer
Co-Chair
MICAA Health Care Committee

cc: Jim Hart
Joan Sanow
Sabrina Ahmed
MICAA members (via email)
Pamela Kassing, ACR
Diane Millman, ASE

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The University of Texas Medical Branch

SCHOOL OF MEDICINE

DEPARTMENT OF INTERNAL MEDICINE
Division of Cardiology

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APC/P-D
Pymt/Revis
S/I

September 12, 2005

Heyster
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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare proposed device reimbursement in hospital outpatient payments for 2006.

University of Texas Medical Branch (UTMB) is a 750 bed acute care tertiary hospital located in Galveston, Texas. As a major health care provider in our local area, we implant medical devices and perform other procedures on a number of Medicare beneficiaries in the outpatient setting. I am writing to express my concerns with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule", published in the Federal Register on July 25, 2005.

Implantable Cardioverter Defibrillators (ICDs)

In the proposed rule, the payment rates for procedures involving some devices were significantly decreased. As a health care provider of these services, these payment reductions are a serious concern. Changes should be made to the 2006 proposed payment rates for ICDs to be more closely aligned with the actual costs involved in providing these devices and services.

In the proposed rule, CMS recommends a decrease of 14.1% from last year's rate for ICD devices. Payment decreases of 14% from one year to the next are problematic on their face and can not be justified, particularly when the 2005 rates show a 2.3% reduction from the year before. No aspect of health care has dropped that much in two years. The resulting APC rates are lower than our institution's cost for the ICD device, leaving us with a loss for the device acquisition cost and no payment for our procedural costs. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To rectify this issue, our facility requests that CMS calculate the 2006 payment rates for ICD implant procedures using 2005 payment rates plus the 3.2% hospital update. I understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates would be more in line with our facility's costs of performing these services.

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Single Procedure Claims
In the proposed rule, CMS requested comments on the February 2005 APC Advisory Panel recommendation to increase the single bills available for rate setting to improve the accuracy of median costs for APCs 0107 and 0108. Although the scenarios displayed in the proposed rule may increase the number of single bills used for rate setting, single procedure claims have not resulted in adequate payment since APCs were established. We are therefore unable to support the proposal.

Left Ventricular Leads
For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resychronization pacing and defibrillation systems (CPT 33225) from APC 1525 to APC 0418. Although the payment rate for the implant would increase from $3,750 to $6,458 with the proposed change in APC, the move to the new APC actually equates to a lower rate of reimbursement overall than the procedure was paid in 2005 ($3,229 v. $3,750) as the status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios.

The assignment of status indicator "T" does not adequately compensate hospitals for additional procedural time and resources associated with this service. The implant procedure for the cardiac resynchronization pacing and defibrillator systems parallel that of a conventional dual chamber pacemaker or ICD with the exception of the implantation of a left ventricular lead and are therefore not duplicative.

Unlike conventional RA and RV leads the implant of a LV lead entails accessing an additional ventricle than that of a conventional pacemaker and defibrillator implantation; requiring transvenous placement in a cardiac vein via the coronary sinus. The additional approach to a coronary vein via the coronary sinus requires additional tools, mapping via venography and a different approach and technique to implant in a coronary vein and additional testing to assure appropriate capture.

The cost of the lead itself, which is the majority of the cost in the APC, is not reduced by 50% when implanted along with other procedures. Please do not change the status indicator for this procedure.

Thank you for this opportunity to provide comments on this very important payment update.

Sincerely,

M Saeed

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NEMA

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September 13, 2005
B-Therapy

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
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Room 314G
Washington, D.C. 20201

ATTN: FILE CODE CMS-1501-P

RE: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS-1501-P); Proposed Rule

Dear Administrator McClellan:

The National Electrical Manufacturers Association (NEMA) wishes to express its appreciation to you for the opportunity to comment on the proposed rule pertaining to Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates. (Federal Register, Vol. 70, No. 141, July 25, 2005).

NEMA is the largest U.S. trade association representing America's electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents over 95% of the market for x-ray imaging (including mammography), CT, radiation therapy, nuclear medicine imaging, diagnostic ultrasound, magnetic resonance and medical imaging informatics equipment.

We appreciate the conscientious efforts that CMS has made in the development of the proposed rates for 2006 and we especially commend CMS's handling of a number of issues that historically have been troublesome for our members. For example, we note that the proposed rule would retain the current payment rate for positron emission tomography (PET) and would implement increased payment levels for proton beam therapy and various external beam radiation therapy procedures. We are particularly pleased that this year's rule appears to include more stable APC rates and we are hopeful that unpredictable APC payments can be avoided in the future.

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Our comments this year relate primarily to CMS's process for establishing APC rates for new technologies-an area of significant interest for NEMA members. In addition, we offer our views on certain services for which hospital charges do not appear to reflect resource costs and on a number of important policy issues.

I. New Technology Issues

A. New Technology APCs

In the HOPPS rule, CMS has proposed an additional requirement for applicants seeking a New Technology APC. The agency proposes that applications for a New Technology APC must be accompanied by a completed CPT code application to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. In addition, the applicant for a New Technology APC must file with CMS, as part of the application for a New Technology APC, a letter that AMA has accepted the application for review.

NEMA has a number of concerns with this proposed policy. First, imposition of this added requirement will impede, rather than enhance, the recognition of new technologies by imposing delays on CMS decisions. Second, the CPT code development process is not public. The AMA CPT Editorial Panel is a private organization. Neither the deliberations by AMA on granting new CPT codes, nor the bases for their decisions, are open to the public. There is no medical industry representation on the AMA CPT Editorial Panel. The AMA CPT Editorial Panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act or the Federal Advisory Committee Act, and thus may not be accountable as are other agencies that are responsible for public policy decisions.

Category I codes are usually assigned to a procedure that has become an accepted standard of care. This defeats the purpose of adoption of new technology. A New Technology APC would likely be assigned a Category III. "emerging technology" code due to lack of availability of sufficient data. This means that the new service may not receive reimbursement by local Medicare carriers, commercial payors and fiscal intermediaries, until a Category I code has been assigned.

NEMA recommends that CMS eliminate this proposed requirement to submit a CPT application to the AMA prior to submitting a New Technology APC application.

NEMA also has a concern regarding premature assignment of a technology to a clinical APC, instead of a New Technology APC, specifically the assignment of a new Category III CPT code immediately to a clinical APC. This conflicts with CMS policy, which states that new technologies be placed in a New Technology APC until adequate data is collected. An example of premature assignment involves MR-guided focused ultrasound for the treatment of uterine fibroids. Effective July 1, 2004, the AMA awarded two new CPT Category III codes to report

these procedures, 0071T and 0072T. In the final regulation setting the HOPPS payment rates for 2005 (Federal Register Vol. 69, No. 219, November 15, 2004), CMS immediately assigned these codes to APC 193, and proposes the same assignment for 2006. This assignment was determined in the complete absence of claims data. In fact, according to the sole manufacturer of the technology, no hospital claims data were generated for these codes during calendar year 2004 - the year for which data are used to determine the HOPPS proposed rates for 2006. (Insightec comments to the APC Advisory Panel regarding MR-Guided Focused Ultrasound, page 2).

We recommend that new procedures with a Category III CPT code be placed into a New Technology APC, based on external data provided. Assignment to a clinical APC should not occur until sufficient claims data has been provided. In addition, we propose that CMS establish a formalized process for soliciting public comment on placement of new codes regardless of whether they are Category I or Category III CPT codes.

B. PET/CT

PET/CT has emerged as one of the most important imaging technologies used for the management of cancer patients. This is due to the number of clinical benefits that PET/CT provides compared with conventional PET. The combination of PET and CT into a single device is a breakthrough in imaging because images from a PET scan, which provides information on cell function, metabolism and body chemistry, and a CT scan, which yields anatomic information, can be merged into an image that more accurately identifies and localizes tumors in the body. When the results of a PET scan and CT scan are fused together, they provide the most complete, non-invasive information available on cancer location and metabolism. Patients benefit from PET/CT scans through earlier diagnosis, more accurate staging, more precise treatment planning and improved monitoring of therapy.

In the Hospital Outpatient Quarterly Update Transmittal 514 (issued in March 2005), CMS assigned the three new PET/CT CPT codes (78814, 78815 and 78816) to New Technology APC 1514, at the payment rate of $ 1250, which is $ 100 higher than the payment rate for standalone PET in APC 1513. We commend CMS for deciding to recognize the new CPT codes for PET/CT and for recognizing the increased costs involved in providing PET/CT over standalone PET.

NEMA agrees with CMS that PET/CT should be kept in the New Technology APC classification for CY 2006, but rather than simply continuing the CY 2005 rate, we believe that the payment rate should be based on external resource data.

Based on NEMA data collected by its statistical programs, the cost of acquiring a PET/CT is approximately $ 1.8 million dollars, while the acquisition cost of PET alone is approximately $ 1.2 million dollars. The Academy of Molecular Imaging (AMI) has conducted a data analysis on PET/CT costs which indicates that costs of PET/CT substantially exceed costs for PET alone. We urge CMS to consider the NEMA equipment cost data cost and the analysis conducted by AMI in establishing the appropriate APC classification for PET/CT for CY 2006.

II. Areas Where Charges Do Not Appear to Reflect Costs

A. Brachytherapy

In the 2006 proposed rule, CMS has substantially reduced payment levels for all brachytherapy APCs: Radioelement Applications (312); Brachytherapy (313); and Complex Interstitial Radiation Source Application (651). NEMA has concerns over the accuracy of CMS' brachytherapy data. Claims that had both the brachytherapy procedure and a brachytherapy source "C" code revealed median costs that were 9 percent to 34 percent higher than the average all single-procedure claims for the APC. This suggests that more appropriate and accurate payment rates for brachytherapy APCs could be achieved through use of a correct coding screen. This would be similar conceptually to the screens CMS applied in the past to "device-dependent" APCs. We recommend that CMS re-establish efforts to employ only "correctly coded" claims for rate-setting purposes, where each brachytherapy procedure claim would contain an appropriate brachytherapy source device "C" code(s).

B. CT Angiography

NEMA wishes to again express our concerns about proposed payment levels for CT angiography (CTA) in relation to payment for conventional CT.

The benefit of CTA is that it is able to display the vasculature in a 3D format rather than the two-dimensional cross-sectional images of conventional CT, and without the disadvantage of catheter angiography, which carries greater cost and risk, due to its invasiveness. CTA's capabilities include showing non flow- dependent, anatomic images of arterial and venous vasculature, and additional information regarding the relationship between the vascular anatomy and surrounding bony and soft tissue structures. CTA can describe the length and morphology of atherosclerotic stenotic plaques, which is information which is valuable for use in surgical planning.

CMS removed CTA from APC 0333 in 2003 and assigned it to APC 0662. Since that time, the payment rate for this APC has been set at levels that fail to reflect the relative differences in costs between CTA and CT procedures alone. This situation continued in 2005 and the disparity between CT and CTA reimbursement levels persists in the 2006 proposed rates.

The significant clinical differences between CT and CTA, as well as major differences in resources required for CTA compared with CT, such as imaging workstations and technician time, make clear the need for CTA to be reimbursed at a higher level than CT. CTA involves the resource utilization of CT scanning, plus the added efforts and expenses involved in 3D image post-processing. Thus, CTA charges should always be higher than anatomically similar CT charges.

Unfortunately, due in part to the assignment of CTA into APC 0333, claims data for CTA have been inconsistent, illogical and invalid, with hospital charges set incorrectly relative to CT

charges. Based on an analysis of earlier data, incorrect charge practices by hospitals resulted in a majority of instances that hospitals charged less for CTA than for CT.

Claims data for CTA (APC 0662) is seriously flawed, and should not be used for calculating the reimbursement rate for these procedures. NEMA recommends instead that reimbursement for CTA should be equal to the combined reimbursement for APC 0333 (CT) plus APC 0282 (3D CPT code 76375). Appropriate reimbursement for CTA is essential to ensuring that patients will continue to have access to this important medical technology.

III. Other Policy Issues

A. Imaging Guidance for Vascular Access

In the proposed rule, CMS states that for 2006, CPT code +76937 - Ultrasonic Guidance for Vascular Access, and CPT code +75998- Fluoroscopic Guidance for Venous Access, continue to be assigned a status indicator of "N," thus bundling the payment for these separate imaging studies into the payment for the catheter placement. This proposal conflicts with CMS' decision in the 2003 Final HOPPS rule. There, CMS proposed to accept the recommendations of the APC Panel and provide separate payment in 2003 for all radiology guidance codes designated as "N" in 2002. The APC Panel also concluded, and CMS concurred, that add-on codes should be paid separately. CMS' deviation from its previous policy with regard to assigning a status indicator of "N" to CPT codes +76937 and +75998 creates a disincentive for providers to perform this service when it is medically indicated.

In its June 2001 report, *'Making Health Care Safer: A Critical Analysis of Patient Safety Practices,"* the Agency for Healthcare Research and Quality (AHRQ) cites the use of real-time ultrasound guidance of central venous catheter (CVC) insertion to be one of the top 11 practices needed to improve patient safety. This report indicated that " The majority of CVC insertions are placed using the landmark method" - meaning that no image guidance is used - resulting in unsuccessful insertion in up to 20% of cases. These so-called "blind insertions" have significantly higher rates of serious complications such as arterial puncture, hematoma, pneumothorax and brachial plexus injury. AHRQ concluded that when ultrasound is used to guide CVC insertions, there is a reduction of 78% in the relative risk.

NEMA recommends that the Status Indicator assigned to CPT codes +76937 and +75998 be changed to "S," thus allowing for separate payment of this service when provided in the hospital outpatient setting, and that CPT code +76937 should be assigned to APC 0268—Ultrasound Guidance Procedures and that CPT code +75998 be assigned to APC 0272—Level I Fluoroscopy. Assigning a status indicator of "S" to these codes, and assigning them to clinically appropriate APCs, would ensure that Medicare beneficiaries who need CVC placements would have access to the appropriate image guidance and thus suffer fewer multiple insertion attempts and clinical complications.

B. Re-assign CPT code 93662, Intracardiac ECG (ICE) Procedures, to an appropriate APC

NEMA believes that CPT code 93662, Intracardiac ECG (ICE) Procedures, should not be grouped into APC 0670 with CPT code 92978, Intravascular Ultrasound Procedures, because these two procedures are dissimilar clinically and with respect to resource consumption. The current grouping of these clinically dissimilar procedures with different costs results in too low a payment level for CPT code 93662—and too high a payment level for CPT code 92978. The result is a disincentive to provide beneficiaries access to Intracardiac ECG (ICE) Procedures. Therefore, we recommend that CMS re-examine the codes assigned to APC 0670, and that CPT code 93662 be re-assigned to an APC with a payment weight that more accurately reflects its costs.

There are several reasons why CPT code 93662, Intracardiac Echocardiography (ICE) Procedures, should not be grouped with CPT code 92978, Intravascular Ultrasound Procedures in the same APC.

1. The procedures are not comparable in terms of clinical complexity. As mentioned above, Intracardiac Echocardiography (ICE) Procedures can be used to image the whole heart and its surrounding structures, instead of just a coronary vessel.

    a. The intracardiac echocardiography (ICE) procedure is closely associated with electrophysiology and interventional cardiology procedures (both diagnostic and therapeutic). The ICE procedure provides direct visualization of the heart.

    b. The intravascular ultrasound (IVUS) procedure is an imaging technique in which a miniaturized ultrasound transducer and rotational mirror are mounted on the tip of a catheter and inserted into an artery or vein to produce two-dimensional tomographic images or three-dimensional computer-enhanced reconstruction of planar IVUS images. IVUS procedures are used as an adjunct to coronary/peripheral angioplasty or coronary/peripheral stent deployment.

2. The procedures are not similar with respect to resources.

    a. The costs of IVUS catheters range from $500 to $700. The costs of ICE catheters range from $900 (for catheters with a radial format) to $2,800 (for catheters with a longitudinal format).

    b. The mean and median costs for CPT procedures 92978 and 93662 that CMS has posted on its web site show a marked difference in the costs of these procedures, as well. The CMS data shows that the mean cost for the ICE procedure is $3,349.77, and the true median cost is $2,081.55, while the comparable costs for the IVUS procedure are $1,819.77 and $1,533.52.

c. To group these two clinically dissimilar procedures in the same APC results in an overpayment of the lower cost IVUS procedure and an underpayment of the higher cost ICE procedure—creating a disincentive to provide beneficiaries access to intracardiac ECG (ICE) procedures.

For these reasons cited above, we recommend that CMS examine the logic of including CPT code 93662, Intracardiac ECG (ICE) Procedures, in APC 0670 with CPT code 92978, Intravascular Utrasound Procedures, and that CPT code 93662 be re-assigned to an APC with a payment weight that more accurately reflects its costs.

C. Multiple Diagnostic Imaging Procedures

Currently under HOPPS, hospitals receive the full APC payment for each diagnostic imaging procedure for each service on a claim, regardless of how many procedures are performed using a single modality and whether or not contiguous areas of the body are reviewed. CMS proposes that whenever two or more procedures in the same family are performed in the same session, the first procedure will be paid at the full reimbursement level and the second at a discount of 50%.

NEMA agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. However, the proposed rule does not discuss in detail how the proposal was developed and the 50% reduction determined. Further, it is possible that hospital cost-to-charge ratios and related cost reports already take into account reductions for multiple imaging procedures.

NEMA recommends that CMS delay for at least one year the adoption of the proposed payment reductions for multiple diagnostic imaging procedures and undertake a thorough study of clinical practice patterns to identify those particular multiple diagnostic imaging procedures that should receive reductions in payment, and determine the appropriate amount of such payment reductions.

NEMA wishes to express its appreciation to CMS for giving us the opportunity to share its views with you. NEMA is committed to working with you to enhance the delivery of quality health care to Medicare patients.

If you have any questions, please feel free to contact me at (703) 841-3241, or Richard Eaton of my staff at (703) 841-3248.

Sincerely,

Robert G. Britain

Federation of American Hospitals™

Pymt Rates
APC Gm
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Charles N. Kahn III
President

September 16, 2005

Dr. Mark McClellan
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: CMS-1501-P; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed changes to the hospital outpatient prospective payment system and calendar year 2006 payment rates.

I. Proposed Updates Affecting Payments for CY 2006, 42680 - 42703

A. Recalibration of "APC Relative Weights" for CY 2006, 42680 - 42691

> *"We are proposing to bypass the 404 codes identified in Table 1 to create new single claims and to use the line-item costs associated with the bypass codes on these claims in the creation of the median costs for the APCs into which they are assigned."*

The FAH commends CMS for their attempts to identify additional methods to create single APC claims and approves of the use of the empirical standards CMS used to develop the list of HCPCS in Table 1 that were ignored to create pseudo single procedure claims. The FAH approves of the use of the process of bypassing the codes in table 1 in order to create "pseudo" single claims and approves of the use of the line-item costs associated with the bypass codes for the creation of the APCs into which the bypass codes are assigned. Again, the FAH commends CMS on continuing to develop techniques that allow the

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use of more claim data to set payment rates. However, we strongly recommend CMS eliminate the requirement that hospitals bill separate OPPS encounters on the same day on a single claim to Medicare. This requirement places administrative burden on the facilities to identify these encounters and combine the services for billing purposes. Additionally, it creates multiple APC claims that may not be usable when CMS establishes payment rates. Elimination of the requirement to combine distinct encounters to a single claim would remove burden from the facility and improve claims data for CMS.

> *"We also excluded ...claims containing token charges (charges of less than $1.01) or for which intermediary systems had allocated charges as if the charges were submitted on the claim. We are proposing to delete claims containing token charges. We do not believe that a charge of less than $1.01 would yield a cost that would be valid to set weights for a significant separately paid service."*

While the FAH agrees in general principal with CMS' proposal to exclude claims with token charges, we are concerned about exclusion of claims containing multiple surgical or cardiac catheterization lab services. CMS has allowed providers to report multiple procedures performed in the same session with a single charge under the revenue code (e.g. 360) that describes where the procedures were performed on the same line with one of the surgical procedure HCPCS codes and the other procedure HCPCS codes with the same revenue code but with zero or token charges on the subsequent charge lines. While many of these claims may be excluded in the recalibration process due to multiple APCs on the claim, there may also be claims with a single paid APC and one or more packaged surgical procedures in the same revenue center. For instance, a cardiac catheterization procedure requires the reporting of multiple CPT codes to describe the procedure performed and generally all but one of the CPT codes is packaged.

Since CMS allows OPPS hospitals to report multiple surgical services with a single charge amount and the additional charge lines are allowed to have zero or token charges, the FAH does not believe it is appropriate to eliminate these claims in the rate setting process. We believe that CMS must use claims that have a token or zero charge present when the token or zero charge is associated with a revenue code on the claim that is repeated and only one charge line for the revenue code has a charge greater than $1.01 and only one charge line for the revenue code is paid by APC. This will help ensure that CMS uses all appropriate single APC claims and packages all appropriate charges when establishing payment rates for services which require the reporting of multiple CPT codes in order to describe the procedure.

The FAH supports the elimination of claims containing token or zero charge lines when there are no other payable services reported with a charge amount under the same revenue code.

> *"...we are proposing to pay separately for CPT code 51701...,...51702 and 51703...we are proposing to accept the APC Panel recommendations that CPT codes 77790 (Radiation handling), 94760 (Pulse oximetry for oxygen saturation, single determination), and 94761 (Pulse oximetry for oxygen saturation, multiple determinations) remain packaged...we are proposing to ...review CPT codes 94762, 42550, and 38792 with the Packaging Subcommittee."*

The FAH commends CMS for their proposal to pay separately for CPT codes 51701-51703. Furthermore, we appreciate CMS's willingness to gather data and review CPT codes 94762, 42550, and 38792 with the packaging subcommittee. However, we strongly recommend CMS reevaluate their stance on packaging pulse oximetry codes 94760 and 94761, as well as 94762. Patients requiring home

oxygen therapy must have diagnostic tests performed to show the medical necessity of home oxygen therapy. These patients are referred by their physician to the hospital outpatient department for single or multiple determination pulse oximetry in order to determine their oxygen saturation levels and this is the only service provided in these encounters. Currently, hospitals provide this service to Medicare beneficiaries but receive no reimbursement for the services provided. Additionally, some of these patients may require overnight pulse oximetry monitoring to determine whether there is a need for home oxygen therapy. In some instances, the hospital outpatient department directs these services in the patient's home similar to the home pulse oximetry monitoring by IDTFs described in Change Request 3751.

Therefore, we recommend that CMS change the status indicator for all three pulse oximetry codes to "Q" indicating these codes are packaged services that will qualify for separate payment when they are the only service provided. This will allow hospitals to receive separate payment for these CMS required diagnostic tests without decreasing the number of single claims available for use in calculating median costs for other services. Additionally, the FAH requests CMS clarify whether hospital outpatient departments may also direct and report 94762 for self administered home based overnight pulse oximetry tests. We would like published clarification from CMS if hospital outpatient departments are to follow the same guidelines specified in CR 3751 or if these rules apply only to Independent Diagnostic Testing Facilities (IDTF).

> *"We referred CPT code 97602 (non-selective wound care) for MPFS evaluation of its bundled status as CPT code 97602 relates to services provided under the OPPS. CPT code 97602 is assigned status indicator "A" in this OPPS proposed rule, meaning that while it is no longer payable under the OPPS, it is payable under a fee schedule... nonselective wound care services described by CPT code 97602 are "bundled" into the selective wound care debridement codes..."*

The FAH strongly recommends CMS review the assignment of status indicator A to CPT codes 97602, 97605, and 97606 (active wound care management with non-selective debridement or negative pressure wound therapy per session) for payment under the MPFS. The services described by CPT code 97602, 97605, and 97606 are frequently performed in outpatient hospital departments (i.e., wound care centers) by licensed wound care nurses incident to physician services. CMS notes in the proposed rule that CPT code 97602 is packaged into the selective wound care debridement codes 97597 and 97598 (active wound care management with selective debridement per session). The FAH disagrees with this statement because the coding guidelines indicate that CPT 97602 would not be separately reported with CPT code 97597 or 97598. Typically, when the services performed meet the definition of CPT codes 97602, 97605, or 97606, no other service is reported. These non-selective debridement and negative pressure wound therapy CPT codes describe a complete service including wound assessment, cleansing, treatment, topical applications, dressing of the wound and instructions for ongoing care. These comprehensive codes are per session not per wound and according to the AMA, each of these procedures typically involve up to 30 minutes of direct one-on-one contact with the patient.

Additionally, according to the AMA, non-physician practitioners performing active wound care management services are to report the appropriate CPT code from the range 97597 – 97606. Because the 97602, 97605 and 97606 active wound care management CPT codes have been classified under the MPFS as always therapy services, they are not covered by the Medicare program when performed by

licensed wound care or enterostomal nurses incident to physician services. CMS has not classified CPT codes 97597 or 97598 as always therapy services. This means selective debridement services performed by licensed wound care or enterostomal nurses are covered by the Medicare program.

However, the active wound care management services that include non-selective debridement or negative pressure wound therapy (i.e., a less intensive service) are not covered when performed by anyone other than a physical therapist. CMS has indicated that this applies even when the services are performed incident to a physician's service and has also indicated that it is inappropriate to report non-covered services under another CPT code, such as an E/M code (11/15/04 Federal Register, Physician Fee Schedule). When CPT 97602 was assigned status indicator N under the OPPS, CMS allowed the reporting of a low level E/M CPT code when the non-selective debridement was the only service provided, but this is no longer allowable under the physician fee schedule rules. Provider based wound care clinics cannot continue to treat patients with non-healing wounds if they receive no payment for the services rendered.

CMS should modify their current handling of the active wound care management CPT codes and allow separate payment under the OPPS. The FAH believes the active wound care management CPT codes 97602-97606 should not be paid under the MPFS when performed in an OPPS hospital and that the codes are misclassified as always therapy services. The FAH believes these services should be modified to represent sometimes therapy services and should be assigned a status indicator of S and paid separately under the OPPS. The FAH recommends CMS assign CPT code 97602, 97605, and 97606 to new technology APC 1502 until claims data is obtained to assign an accurate payment amount based on median costs.

B. Proposed Payment for Partial Hospitalization

We are concerned that proposed changes to the outpatient prospective payment system (PPS) could negatively affect the partial hospitalization benefit. Although providers are committed to finding ways to ensure that their patients have access to this essential level of care, partial hospital capacity in the behavioral healthcare system remains a concern. Many partial programs have closed or limited the number of patients they can accept, and fewer partial hospital slots now exist nationwide.

We appreciate the various approaches CMS considered in the 2006 proposed rule in dealing with the complexities of the historical cost data supplied by hospital and community mental health center (CMHC) providers of the partial hospitalization benefit. We agree that the range of data provided by the CMHCs throughout the last five years (with a median per diem cost ranging from a high of $1,037 to a low of $143) has made it difficult to determine actual costs. We are aware of the various strategies CMS has applied in dealing with the CMHC data, including adjusting cost-to-charge ratios, examining the influence of outlier payments, and recognizing the significant drop in the cost per day.

Based on the clinical intensity of the PHP benefit, we do not understand how it could possibly be provided for $143. This figure raises serious questions about the accuracy of the data reported on CMHC cost reports. By regulation, PHPs are required to provide a program of active treatment which includes at least three individualized treatment sessions per day, in addition to appropriate individual

therapy and treatment planning. This level of intensity closely mirrors the care provided in an inpatient treatment setting. Were it not for the existence of partial hospitalization, beneficiaries would be hospitalized.

We noted the various ways CMS proposed to deal with the complexities of determining an updated payment rate (such as following the methodology used for the CY 2005 OPPS update, basing the update on hospital-based PHP data alone, or applying different trimming methodologies to CMHC cost data in an effort to eliminate aberrant data and decrease the instability in CMHC data).

We noted the desire of CMS to lessen the PHP payment reduction for CY 2006, so that you can ensure an adequate payment amount and continuing access to the partial hospitalization benefit for Medicare beneficiaries. CMS proposed a reduction of 15% as a way of doing this. The rationale for this reduction (from $289 to $245.65) states that CMS thinks this will recognize the decrease in the median per diem costs in both the hospital and CMHC data and also reduce the risk of any adverse impact on access to these services that might result from a large single-year rate reduction. CMS further states that it will continue to work with CMHCs to improve their reporting so that payments can be calculated based on better empirical data.

The basis of a prospective payment system is to provide stability and predictability in payment in order to encourage efficiency in the delivery of services and to allow providers to budget and plan for the provision of services. A PPS system is not designed to endure significant adjustments every year based on historical costs. Changes of the magnitude of 15% undermine the basis of the system. Providers and payers alike need to be able to rely on a predictable methodology for determining payment that will allow the PHP benefit to be available to Medicare beneficiaries in a stable way. This methodology needs to be predicated on reliable data.

Selecting the 15% reduction may protect providers from more onerous cuts, but it is in itself not an acceptable solution. The volatility in the CMHC data continues to be inadequately explained.

There are many administrative costs (transportation, food) that are not Medicare-reimbursable. But they are real costs to the provider and need to be considered as payers and providers analyze the fiscal realities of providing the benefit. There are also highly prescriptive administrative and regulatory responsibilities that providers must meet in order to offer the benefit. These, too, contribute significantly to costs. Especially in the new era of Medicare inpatient psychiatric prospective payment, it is very important there be a strong alternative to hospitalization. Partial hospitalization *is* that alternative.

Recommendations

1. To allow the time and resources necessary to fully develop an adequate payment methodology, we propose that the 2006 PHP payment rate remain the same as the 2005 rate--$281.33. We would continue to work with CMS and others to study the data and refine the methodology to develop a payment rate that is fair and predictable.

2. Strategies that may be considered in the development of PHP rates could include the following:

- Use inpatient costs per day as the basis for the PHP median cost per diem. CMS could apply to the IPF PPS cost per diem a scaling factor (perhaps 50%) to develop a basis for the PHP median cost per diem. CMS would, in effect, develop a corollary factor between the PHP cost and inpatient psychiatric cost.

- Develop a cost method that uses, as an example, a three-year rolling average of the CMHC PHP cost per diem. This would use an average cost over time rather than a cost that has changed dramatically from year to year.

3. The successful use of any revised methodology would be dependent on developing a method for improving future CMHC cost report information. We recommend that CMS review and revise the various forms and worksheets used by CMHCs to report data. Specifically, CMS should:

a. Revise the CMHC cost report form (CMS-2088) to include a field which allows the CMHC to report its Medicare PHP days. The existing worksheet S-7, Part IV (Statistical Data) could be modified to include this new field. This field would be similar to the CMS- 2552-96 worksheet S-2, Part I field in which outpatient "Observation Bed Days" are reported. This information would then be subject to Medicare fiscal intermediary review and validation as part of the cost report desk review and audit process.

b. Revise settlement worksheet D on the CMS-2088 to include new fields that 1) display the Medicare PHP cost per day and 2) separate PHP reimbursement between outlier and non-outlier reimbursement (since the current cost report form commingles both types of reimbursement). This data will provide CMS and the provider with a quick snapshot of the facility's cost and payment per diem data. This new information will help in the Medicare fiscal intermediary's evaluation of the cost report data if any of the cost or payment PHP per diem amounts appear to be aberrant.

c. Revise the CMHC Provider Statistical & Reimbursement Report ("PS&R") Report Type: 76P to include a field which reports actual paid Medicare PHP days. This information can then be used by the provider and fiscal intermediary for the CMHC cost report submission and final settlement.

D. Proposed Wage Index Changes for CY 2006 42695 – 42696

"We are proposing to adopt the IPPS wage indices and extend these wage indices to TEFRA hospitals that participate in the OPPS but not the IPPS"

The FAH commends the CMS for their proposal to extend the IPPS wage indices to OPPS as they have done in previous years. This administratively simplifies the payment process for providers. In addition the FAH agrees with CMS opinion that "that using the IPPS wage index as the source on an adjustment

factor for OPPS is reasonable and logical, given the inseparable, subordinate status of the hospital outpatient within the hospital overall." Any concerns in the wage index area can be raised and dealt with in the development of the IPPS rule.

The FAH also recommends that CMS follow the same reclassification process for 508 hospitals for calendar year 2007 that it has specified in the IPPS final regulations in the August 12, 2005 federal register on pages 47382 and 47383 for OPPS.

H. Proposed Hospital Outpatient "Outlier Payments", 42701 - 42702

"For CY 2006, we are proposing to set our projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS."

For CY 2006, CMS has proposed to set the projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS. In CY 2005, CMS had set the aggregate outlier payments at 2.0 percent of aggregate total payments. FAH is in agreement with setting the aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS and commends CMS for making this proposed change.

However, FAH is concerned with the methodology that CMS used to set the outlier threshold in CY 2005 and has proposed to continue to use for CY 2006. For CY 2005, CMS has estimated that actual outlier payments will be 1.0 percent of total payments, which is 50% below the 2.0 percent that CMS set as the target for outlier payments. CMS has employed a methodology (charge inflation model) that inflates charges for CY 2004 claims for two years and then applies the latest hospital specific ratio of cost to charges (RCCs) to such charges to model the outlier threshold for CY 2006. Such charge inflation model is seriously flawed in that it fails to consider the decline in the RCCs that will occur as a by-product of inflating the charges.

FAH recommends that CMS revise their outlier model to include a projected decline in the RCCs that will result from projecting charge increases to inflate claims from CY 2004 to CY 2006. FAH made extensive comments on the same basic payment model that is used for IPPS (with the same significant underpayment results) and refers CMS to our comment letter dated June 24, 2005 to the proposed IPPS rule for FY 2006 for more in-depth discussion of the flaws with the currently used model.

In that comment letter, FAH engaged Vaida Health Data Consultants to evaluate the CMS model and to model the outlier threshold using a declining RCCs model as part of the current charge inflation model. Such research showed the results not only of the projected outlier threshold for FY 2006 but also showed that such declining RCC model would have produced more accurate actual payments if it had been used for prior years. Thus, FAH strongly recommends that CMS incorporate declining RCCs into their current charge inflation model to establish the fixed loss threshold and the multiple threshold (i.e. 1.75 times the APC payment).

CMS published the statewide average cost-to-charge ratios in Table 3 on page 42696 of the Federal Register dated July 25, 2005. CMS discloses that there has been an overall decrease in the default statewide RCCs.

"The overall decrease in default statewide CCRs can be attributed to the general decline in the ratio between costs and charges widely observed in the cost report data."

This Table documents the significant decline that has occurred and is occurring in RCCs and which CMS has not taken into consideration in its current charge inflation model. Unless CMS incorporates a decline in the RCCs into their charge inflation model, CMS will continue to underpay outliers under the target that is set (i.e. 1.0 percent for CY 2006).

CMS has proposed to revise the fixed dollar threshold from $1,175 for CY 2005 to $1,575 for CY 2006. The threshold of $1,575 was developed by using a charge inflation factor of 18.04 percent to model the proposed CY 2006 outliers at 1.0 percent of total payments. CMS had proposed the same inflation factor of 18.04 percent in the IPPS proposed rule. However, in the final IPPS rule as published in the Federal Register on August 12, 2005, CMS revised the inflation factor from 18.04 percent to 14.94 percent. FAH recommends that CMS revise the outlier threshold to reflect the inflation factor of 14.94 percent for OPPS, the same inflation factor as used by CMS for IPPS.

In the IPPS final rule, CMS also revised the fixed loss threshold to reflect the RCCs contained in the latest available hospital specific data file. CMS should likewise revise the proposed outlier fixed loss threshold by updating the RCCs for OPPS to the latest available hospital specific data.

II. Proposed Ambulatory Payment Classification (APC), 42703 - 42713

C. "New Technology APCs", 42707

"...we are proposing to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA's) CPT Editorial Panel before we accept a New Technology APC application for review."

The FAH agrees with CMS on the decision to require a submission to the AMA CPT Editorial Panel prior to accepting an application for a New Technology APC. We recommend CMS finalize this proposal.

C. 4 (b) "Stereotactic Radiosurgery", 42708 – 42709

"Therefore, we are proposing to discontinue HCPCS codes G0242 and G0338 for the reporting of charges for SRS planning under the OPPS, and to instruct hospitals to bill charges for SRS planning using all of the available CPT codes that most accurately reflect the services provided."

The FAH supports the elimination of the G-HCPCS codes for SRS planning. The FAH supports the use of level one HCPCS (CPT) codes for reporting OPPS services to simplify the coding and billing process for OPPS hospitals.

D. Proposed APC-Specific Policies, 42710 – 42712

1. "Hyperbaric Oxygen" Therapy, 42710

"...we calculated a 'per unit' median of $93.26 for HBOT, using only multiple units or multiple occurrences of HBOT and each hospital's overall CCR."

The FAH supports the elimination of claim anomalies when establishing the appropriate median costs for HBO Therapy. We commend CMS for their attempts to establish appropriate rates for OPPS services.

2. "Allergy Testing", 42710

"Therefore, we are proposing to move the allergy test CPT codes that instruct providers to specify the number of tests or use the singular word 'test' in their descriptors form APC 0370 (Allergy Tests) to proposed APC 0381 (Single Allergy Tests) for CY 2006."

The FAH supports the proposed movement of allergy test CPT codes into two APC configurations to differentiate between CPT codes that represent "per visit" and "per test" services. We strongly recommend CMS provide education to OPPS hospitals to ensure hospitals are reporting these CPT codes appropriately.

III. Proposed Payment Changes for Devices, 42713 – 42721

A. "Device- Dependent APCs", 42713 – 42715

"Therefore, for the CY 2006 OPPS, as we have consistently done for device-dependent APCs, we are proposing to adjust the median costs for the device-dependent APCs listed in Table 15 for which comparisons with prior years are valid to the higher of the CY 2006 unadjusted APC median or 85 percent of the adjusted median on which payment was based for the CY 2005 OPPS."

The FAH supports the proposed median cost adjustments for device-dependent APCs for CY 2006. The FAH commends CMS on their continued analysis of the issues surrounding device-dependent procedures. The FAH recognizes that the fold-in of medical devices into specific APCs for outpatient prospective payment reflects an averaging process. CMS has used charges from the 2004 Medicare claims to compute the relative APC weights. The APC weights were determined by applying a hospital specific cost to charge ratio by department to the charges as reflected on the 2004 claims.

A hospital's cost mark up to arrive at billed charges may be more or less for new technology versus other billed items. Thus, the use of the hospital's average cost-to-charge will result in computed costs and APC weights to be more or less than specific actual cost. This averaging is appropriate and desirable in a prospective payment system. The alternative is a micro-managed payment system that resembles the cost-based reimbursement system that Congress discarded in favor of a bundled PPS. The FAH recommends that CMS stay committed to the principles of prospective payment and the use of the averaging process rather than seeking to pay actual cost for one element of costs (new technology) at the expense of all other items which would result after application of mandated budget neutrality adjustments.

B. APC Panel Recommendations Pertaining to APC 0107 and APC 0108, 42716-42717

As stated previously, FAH supports the use of hospital specific data to establish the APC payment rates. FAH recognizes that the use of hospital specific cost to charge ratios will compute costs and APC weights that are more or less than "actual costs". However, FAH believes that this averaging process is appropriate and desirable in a prospective payment system.

FAH has also expressed support for the use of more multiple procedure claims to establish APC weights. The APC Panel recommended that CMS package CPT codes 93640 and 93641 (electrophysiologic evaluation at time of initial implantation or replacement of cardioverter-defibrillator leads). The APC panel also recommended that CMS treat CPT code 33241 (Subcutaneous removal of cardioverter-defibrillator) as a bypass code when the code appeared on the same claims with services assigned to APC 0107 and APC 0108. FAH is supportive of the recommendations of the APC Panel that would permit more robust set of single bills to set the weights for APC 0107 and APC 0108.

IV. Proposed Payment Changes for Drugs, Biologicals, and Radiopharmaceutical Agents, 42721 –42735

B. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status "NonPass-Throughs", 42723 – 42732

"...we are proposing to establish three distinct HCPCS C-codes and three corresponding APCs for drug handling categories for drugs and biologicals, by combining several of the categories identified in the MedPAC report...We are proposing to instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with each administration of each separately payable drug and biological based on the code description which best reflects the service the hospital provides to prepare the product for administration to a patient...We are specifically seeking comments on this proposed policy for paying for pharmacy overhead costs in CY 2006 and on the proposed policy regarding hospital billing of drug handling charges associated with each administration of each separately payable drug or biological using the proposed C-codes."

The FAH is strongly opposed to the addition of C-codes requiring hospitals to report drug handling charges in order for CMS to pay pharmacy overhead costs. The proposed methodology raises several concerns as outlined below:

- Required charge structure: A principal tenet of the Medicare Act in 42 U.S.C. 1395 prohibits "any Federal officer or employee to exercise...any supervision or control over the administration or operation of any such institution, agency, or person." This has commonly been understood by CMS as prohibition of any interference with hospital charge structures. CMS states in CMS Publication 15-1, The Provider Reimbursement Manual, Section 2203, that "the Medicare program cannot dictate to a provider what its charges or charge structure may be." By proposing to require hospitals to bill a handling charge when the industry practice has

been to bill a combined charge to reflect both drug acquisition cost and handling cost is a contrary to this basic, long standing tenet.

- Consistent charge structure: Medicare providers must have a consistent charge structure in order to prepare the Medicare cost report. Consistent charges are needed to apportion costs within the Medicare cost report. The proposal by CMS to require hospitals to begin billing the drug handling charge as a separate line item charge will present billing and payment concerns for all other payers. For example, such drug handling charge would have to be billed to private pay payers and the Medicaid program or the provider would have to be able to generate consistent charges for proper Medicare apportionment of costs. Most other payers (including the Medicare program for non-OPPS claims) do not recognize C-codes and may refuse to accept and/or pay for such handling charge. This raises the dilemma as to whether or not the hospital must pursue collection (similar issue to charity, uncompensated care charges) in order to have a consistent charge structure for payment and apportionment.

- Current charge structure: As recognized by CMS and by MedPAC, drug handling costs are not presently separately billed by the vast majority of hospitals. The vast majority of hospitals do not have sophisticated cost accounting systems that would permit the determination of handling costs for each billable drug. The pharmacy chargemaster for most hospitals contains several thousand line items. It would be a tremendous burden to hospitals to require the modification of their pharmacy chargemaster to reduce each current drug charge to reflect only the drug acquisition costs. This would require hospitals to identify and remove the drug handling costs currently included in each drug line item's charge. Hospitals that do not have sophisticated cost accounting systems will have difficulty in determining the applicable amount that is attributed to the handling costs. Additionally, the volume of drug charge lines that will require modification will require tremendous time and resources for each hospital.

  Even if the administratively burdensome process of billing for handling charges is adopted by CMS, FAH is convinced that CMS will still be unable to determine drug handling costs at the individual drug level. CMS will still apply an average Pharmacy department RCC to billed charges to determine drug handling costs. While RCCs can adequately determine costs in total (for a total hospital department, such as Pharmacy), RCCs were never intended to determine cost at the procedure level, such as drug handling cost for individual drugs.

- Separately paid drugs only: CMS has proposed to pay the drug handling costs only for those drugs which receive separate payment under the OPPS. This creates an additional burden for facilities since they must identify and modify only those drug charge items that qualify for separate payment under the OPPS. Charges for packaged drugs must continue to include the overhead costs as part of the drug's line item charge. This will require continual maintenance of drug line item charges by hospitals since the pharmacy items that qualify for separate payment fluctuate under the OPPS system on an annual and sometimes quarterly basis.

- Drug handling future rates: CMS has proposed to require hospitals report the drug HCPCS code, the drug handling category HCPCS code and the drug administration HCPCS code (if applicable). This creates an additional level of complexity to an already complex system. It also will create fewer single APC claims and/or result in additional requirements for bypassing

procedures to produce pseudo-single claims. Because Medicare beneficiaries frequently require more than one drug in an outpatient encounter, it may be impossible to identify any correlation between the drug HCPCS code reported and the drug handling category HCPCS code reported. Additionally, since neither the presence nor accuracy of the drug handling HCPCS codes will impact the proposed 2006 payment of drug handling costs, hospitals will have no incentive to perform the chargemaster maintenance and education of pharmacy staff that will be required to provide CMS accurate claims data.

CMS has indicated their intent to apply the pharmacy hospital cost to charge ratio to the billed handling cost charges to determine and evaluate the handling cost for future payment. This will only work reasonably well if hospitals can reasonably estimate their drug handling cost and if hospitals markup their drug handling costs in line with their overall pharmacy markup. There is also an issue if hospitals report the new drug handling costs separately without restructuring their existing drug charges to remove the drug handling costs already included in the drug charges.

Because of the issues raised above the FAH strongly opposes the addition of the drug handling C-codes and recommends CMS find an alternative method to identify drug handling costs. FAH recommends that CMS adopt a process similar to what CMS describes was used to support the 2 percent payment for CY 2006. Since CMS and MedPAC recognize that drug handling costs are already included in the drug charge and the drug handling cost is already reflected in the Pharmacy department on the Medicare cost report, CMS could simply compute a reasonable estimate of handling costs by use of the current cost report by first computing the mean cost of each drug and then deducting the ASP+6%. After excluding statistical outliers, CMS would have a reasonable estimate of the handling costs either by drug HCPCS code or by the three categories without hospitals incurring the additional burden of billing a new handling charge. CMS could then add the estimated handling costs to the drug ASP+6% payment to create a payment for acquisition costs and handling costs. This method should also be more accurate than the current proposal of 2% of ASP for handling costs that applies equally to all three categories.

The FAH is concerned the proposed 2% of ASP for handling costs is significantly lower than the percentage indicated by the both the MedPAC and CMS studies. In their report to Congress, MedPAC concludes handling costs are "not insignificant". On the contrary, the relatively immaterial 2% amount proposed by CMS conflicts with the Med PAC conclusion. Since drug handling cost must be paid in a budget neutral manner, FAH questions the adoption of an administratively burdensome process which attempts to redistribute OPPS payments for only 2% of drug payments. Thus, if CMS continues to believe its data indicates that drug handling costs are only 2% of drug payments, the FAH recommends CMS withdraw its proposal which requires the billing of handling charges and simply adopt the 2% payment process proposed for CY 2006 and for future years. When reviewing the cost-benefit analysis of the CMS proposal, it's clear the cost of CMS' proposed new process is too burdensome for such a relatively small payment refinement benefit.

V. "Estimate of Transitional Pass-Through Spending" in CY2006 for Drugs, Biologicals, and Devices, 42735

"...we are proposing to return 1.95 percent of the pass-through pool to adjust the conversion factor..."

The FAH commends CMS for returning the portion of the pass-through pool which exceeds the estimated amount required for pass-through payments in CY 2006 to adjust the conversion factor. Returning this money to the pool helps ensure beneficiary access to basic OPPS services.

VI. Proposed Coding and Payment for "Drug Administration", 42737 - 42740

"...we are proposing to continue our policy of using CPT codes to bill for drug administration services provided in the hospital outpatient department. We anticipate that the current CPT codes will no longer be effective in CY 2006, and therefore, we are proposing a CY 2006 crosswalk that maps current CPT codes to the CPT drug administration codes approved by the CPT Editorial Panel in 2004, which correspond to the G-codes used in the physician office setting for CY 2005 and which we expect to become active CPT codes for 2006."

The FAH commends CMS for their commitment to using CPT codes for drug administration instead of HCPCS level II codes that create additional coding and billing burden for hospitals. CMS has indicated that they are anticipating the CPT code changes for 2006 will match the current G-codes used by physician offices. The FAH strongly recommends CMS use the 2006 CPT codes regardless of any difference in the anticipated and actual published 2006 CPT codes for drug administration. The FAH is in favor of CMS' proposed crosswalk for the anticipated CY 2006 drug administration CPT codes to drug administration APCs. Due to the anticipated changes in the drug administration CPT code descriptions, the FAH strongly recommends CMS publish clear education on how the services should be reported to Medicare prior to January 1, 2006. Clear education from CMS on the reporting of the new drug administration CPT codes will help prevent future issues related to inadequate or incorrect drug administration claims data.

VII. Hospital Coding for Evaluation and Management "(E/M) Services"

"We intend to make available for public comment the proposed coding guidelines that we are considering through the CMS OPPS Web site as soon as we have completed them."

The FAH appreciates CMS' indication that they will allow ample time for comment on the proposed E/M guidelines, however, we strongly recommend CMS follow the proposed rule making process for the E/M guidelines. We believe it is essential to use the rule-making process to ensure recognition of the guidelines by the FIs and the healthcare industry. The FAH recommends that codes and coding guidelines be published in the Federal Register as a proposed rule with an adequate time period for comments, and that the final rule also contain the codes and coding guidelines. This will ensure that codes and coding guidelines are subject to rule making requirements and will allow industry review and comment prior to any future modifications. This will also stress the importance of a national standard to non-Medicare payers.

VIII. Proposed Payment for "Observation Services", 42742-42745

"...we are proposing to discontinue HCPCS codes G0244 (Observation care by facility to patient), G0263(Direct admission with CHF, CPT, asthma), and G0264 (Assessment other than CHF, CP, asthma) and to create two new HCPCS codes to be used by hospitals to report all observation services whether separately payable or packaged, and direct admission for observation care..."

The FAH commends CMS for the proposed coding simplification of observation services. The FAH believes the proposed coding change will reduce the hospital's administrative burden related to accurate billing of observation services in addition to improving claims data for CMS. We also laud the proposal of shifting the determination of whether or not observation stays are separately payable under APC 0339 to the OPPS claims processing logic at the fiscal intermediaries and thereby reducing the administrative burden on hospitals. However, the FAH strongly requests that CMS continue to support and research additional and better methods of paying for observation services.

The FAH strongly recommends that CMS reconsider their decision to require the chest pain, asthma or CHF diagnosis code to be in either the admitting or principal diagnosis code position. The FAH strongly discourages this positioning in the diagnosis coding requirements. Due to the specificity of coding rules and the frequency of Medicare beneficiaries with these specified conditions having many other presenting signs, symptoms, and clinical conditions, we strongly recommend CMS change back to the requirement that the chest pain, asthma, or CHF diagnosis be in <u>any</u> diagnosis code field.

We believe many observation claims for beneficiaries with these conditions will no longer meet the criteria if the position of the diagnosis code is restricted to the admitting or principal field. For example a patient presenting to the ED with nausea and vomiting with a history of coronary artery disease (CAD) may be placed into observation for monitoring of chest pain that develops or intensifies after presenting to the ED. Due to coding rules, the nausea and vomiting will be reported as the reason for visit and the CAD will be reported as the primary diagnosis. The chest pain diagnosis, which would make the patient eligible for separate payment of observation, must be placed in a secondary diagnosis field because coding rules require the reporting of known diagnoses prior to the reporting of signs and symptoms.

We strongly recommend CMS reconsider their decision to only pay separately for the conditions of asthma, CHF, and chest pain when the corresponding diagnosis is reported in the admitting or principle diagnosis field. Furthermore, we request CMS consider the addition of the diagnoses codes for CAD as valid conditions for separate payment of observation.

The FAH requests CMS clarify the additional hospital services required to qualify for separate payment of observation services, because the proposed list on pages 42744 - 42745 excludes the direct admission to observation. CMS has not clearly identified this as a proposed change in the criteria for separate payment for observation, so the FAH believes this was an oversight when CMS listed the requirements. However, if CMS is proposing this change to restrict separate payment of observation services to only those observation encounters that begin with a visit to the hospital's provider based clinic or emergency department, the FAH is strongly opposed to the change.

The FAH commends CMS for proposing to continue paying for direct admission to observation when a Medicare beneficiary is directly admitted into a hospital outpatient department for observation care that does not qualify for separate payment under APC 0339. However, we disagree with CMS proposing

that no services with a status indicator "V" can be on the claim when provided on the same day of service as HCPCS code GYYYY. While we agree that the direct admission assessment HCPCS code should only be reported when the patient is placed in observation by order of a physician without receiving an evaluation and management service within the hospital, we disagree with disallowing payment when a service with a status indicator "V" is present on the same date of service, especially since CMS requires all OPPS services performed on the same date of service to be reported on the same claim. A patient may present to a provider based clinic for an eye examination (e.g. 92012) in the morning and later in the same day may be placed directly in observation by the patient's PCP for abdominal pain. Under current OPPS billing requirements, the hospital must combine the separate patient encounters to a single bill. The FAH recommends CMS eliminate the requirement that hospitals must combine separate outpatient encounters on a single claim to Medicare.

IX. Proposed Indicator Assignments ("Status Indicator"), 42747 – 42748

> *"H" to indicate pass-through devices, brachytherapy sources, and separately payable radiopharmaceuticals that are paid on a cost basis."*

The FAH strongly recommends CMS establish a new status indicator for brachytherapy sources and radiopharmaceuticals paid on a cost basis instead of assigning these to status indicator "H", which was previously used only for devices that are paid under the OPPS transitional pass-through rules. Because brachytherapy sources and radiopharmaceuticals are subject to coinsurance, whereas devices subject to pass-through rules are not, we believe this change promotes consistency in the classification of the status indicators that is not present under the current and proposed classification.

X. Proposed Nonrecurring Policy Changes ("Multiple Diagnostic Imaging Procedures"), 42748 - 42753

> *"We are proposing to apply the multiple imaging procedure reduction only to individual services described by codes within one Family... We are proposing to make full payment for the procedure with the highest APC payment rate, and payment at 50 percent of the applicable APC payment rate for every additional procedure, when performed in the same session."*

The FAH strongly opposes CMS' proposed plan to discount multiple imaging procedures. Any cost economies of performing multiple procedures in the same "family" of imaging procedures by imaging modality and contiguous body parts are currently reflected in the hospital costs that are used to establish the payment weights for these procedures. Because the APC weights are calculated based on the hospital's charges reduced to cost by the facility cost to charge ratio, the APC payment weights already reflect a lower payment rate for any cost savings by the facility. OPPS radiological procedures, whether performed as individual radiological services or in multiples, already receive an average payment rate that accounts for any cost savings when the services are performed in multiples. This averaging is appropriate and desirable in a prospective payment system. The alternative is a micro-managed payment system that resembles the cost-based reimbursement system that Congress discarded in favor of a bundled PPS. Since the payment for radiological services already captures any cost savings associated with performing multiple radiologic services in the same session, the FAH opposes any further reduction to radiologic services.

Additionally, the payment calculation for the technical component of radiologic services paid under the physician fee schedule (MPFS) is based on specific PE inputs of clinical labor, supplies and equipment for each service. The MPFS calculation does not take into account the averaging of costs that is inherent in the OPPS. We believe it is inappropriate to apply the same methodology used for the physician fee schedule payments to the OPPS.

Additionally, equipment costs constitute a significant cost for the imaging families identified for the proposed reduction. These radiological services are capital cost intense unlike surgery which may be more labor and supply intense. The FAH does not believe it is appropriate to apply the same policy of reducing multiple surgical procedures in the same session by 50% to radiology services performed in the same session.

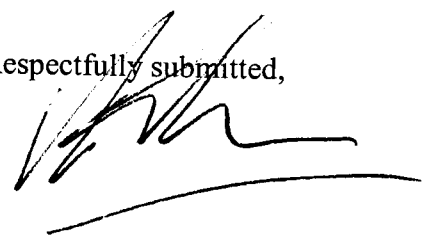
If CMS adopts a policy to reduce radiology services when additional radiology procedures in a family are performed in the same session, FAH strongly recommends that any such reduction should be significantly less than the 50% reduction used for multiple surgical procedures in order to recognize the higher capital costs related to radiology procedures. Additionally, CMS must implement a method to distinguish between radiology services in the same family that are performed in separate encounters on the same day and those performed in the same encounter since CMS requires OPPS services performed in separate encounters performed on the same date of service be combined on a single bill to Medicare. The FAH recommends CMS eliminate the requirement that hospitals must combine separate outpatient encounters on a single claim to Medicare.

Based upon the footnote to Column 2 of Table 33, "Impact of Proposed Changes for CY 2006 Hospital Outpatient Prospective Payment System", (page 42762), which refers to the proposed multiple procedure discounting for radiology procedures, it is our understanding that the proposed change in payment methodology for these services is budget neutral and has been considered in the development of the conversion factor. We would like confirmation that if CMS implements multiple radiological procedure discounting, it will be treated as a budget neutral change in the development of the CY 2006 OPPS conversion factor.

* * * *

FAH appreciates CMS's review and careful consideration of the comments in this letter, and would be happy to meet, at your convenience, to discuss them. If you have any questions, please feel free to contact Steve Speil, Senior Vice President, Health Finance, Policy and Legal Affairs, and Chief Financial Officer at 202-624-1529.

Respectfully submitted,



Pymt Rates levi
DA Burkley
APC/Gen Hostetler
Imaging Hunter
Observation Ritter
BBP Asplen
EM Services
HBOT
Rural Ads
PHP
APC Weights
Outlier

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September 16, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates (70 *Federal Register* 42673), July 25, 2005.

Dear Dr. McClellan:

On behalf of our 4,800 member hospitals, health care systems, and other health care organizations, and our 33,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (OPPS) for calendar year 2006.

Our analysis of the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2006 than in 2005. These changes make it extremely difficult for hospitals to plan and budget from year to year. Among these "broken" APCs, several evaluation and management (E/M) services APCs – especially clinic visits – continue to experience declines in payment rates. We would expect that four years after the start of the OPPS, the payment rates and associated payment-to-cost ratios would be much more stable.

In addition to this instability, the entire OPPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues such as severe workforce shortages, skyrocketing liability premiums, the rising cost of drugs and technologies, aging facilities, expensive regulatory mandates and more. **The AHA will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.**

The proposed rule contains a number of significant policy changes, including changes to payments for handling costs hospitals incur for separately paid drugs, increases in the threshold for the outlier policy, reduced payments for multiple imaging procedures, and changes to payment for rural hospitals. We address these areas briefly in this cover letter and in more detail in the attachment.

PHARMACY OVERHEAD AND DRUG HANDLING PAYMENT RATE ADJUSTMENT

The proposed rule adjusts the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. Since CMS does not have separate hospital charge data on these pharmacy costs, the agency proposes in 2006 to pay 2 percent of the average sales price (ASP) for these products. To set payment rates in the future, CMS proposes three distinct temporary healthcare common procedure coding system (HCPCS) codes (C-codes) and corresponding APCs to differentiate by level of overhead costs for drugs and biologicals. Hospitals would be instructed to charge the appropriate pharmacy overhead C-code when they provide separately payable drugs.

The AHA believes that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We are concerned, however, that the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. **CMS should freeze payments at 2005 levels for those drugs whose payments would decline significantly from the 2005 rates, particularly for those drugs that may have especially complex and costly handling requirements.** We also have serious operational concerns about the requirement that hospitals establish separate charges for pharmacy overhead using the three proposed C-codes. Most importantly, Medicare providers must have uniform charges for all payers (see 70 *Federal Register* 42693), but payers other than Medicare do not use the C-codes. If implemented, this policy would seem to be inconsistent with the requirement stated in the *Federal Register* that "Medicare providers are required to maintain uniform charges for all payers" because providers would now be obligated to maintain different charge structures for drugs – one for Medicare that does not include handling costs and one for other payers that does.

For this and many other reasons outlined in our detailed comments, the **AHA strongly opposes CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs using the three proposed C-codes.** Instead, we recommend that CMS work with stakeholder groups to collect further data and develop simpler solutions. The AHA would be pleased to convene a group of member hospitals to discuss possible alternatives.

OUTLIER POLICY

The AHA also continues to be concerned about the outlier policy. The proposed rule would decrease the set-aside for outlier payments from 2 to 1 percent and increase the dollar threshold for receiving outlier payments by $400, to $1,575. We are concerned about whether the proposed threshold is too high and request clarification on how it was determined. In addition, as in previous years, the proposed rule does not include data on the actual outlier payments made in 2005 and prior years. **The AHA strongly recommends that CMS publish in the final rule data on actual outlier payments made in 2004 and prior years, and that actual outlier payments for 2005 and later years be reported as soon as possible.**

REDUCED PAYMENT FOR MULTIPLE IMAGING PROCEDURES

CMS proposes reducing payment when multiple imaging services are provided on the same day, with full payment for the costliest imaging service and a 50 percent reduction in payment for additional procedures from the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area. In developing this policy, CMS did not examine hospital cost data, but relied on Medicare physician fee schedule practice expense data. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies obtained by hospitals, if they even exist.

The AHA opposes moving forward with this policy without a better justification and more substantial, hospital-based data to support the policy. We would note that the APC advisory panel came to the same conclusion. We also are concerned with the lack of implementation detail provided in the proposed rule, such as defining "the same session." Finally, we would like clarification on how CMS would ensure that this change is budget neutral. The proposed rule provides no detail on how the impact of the multiple imaging procedures discount was calculated or how the budget neutrality factor was adjusted.

CHANGES TO PAYMENTS FOR RURAL HOSPITALS

The proposed rule announces the expiration of hold-harmless payments for small rural hospitals. These are vulnerable facilities that provide important access to care for their communities. The AHA is working with key members of Congress on legislation to permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

The proposed rule also presents the findings of a study on rural versus urban hospital outpatient costs, and concludes that a 6.6 percent payment increase is needed for rural sole community hospitals (SCHs). The AHA is concerned that the supporting analysis in Table 6 of the proposed rule does not separately present findings for rural hospitals with 100 or fewer beds that are not rural SCHs. **We urge CMS to present its findings for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.** The AHA also seeks clarification on whether the 6.6 percent payment increase is affected by hospital reclassifications or participation in the Rural Community Hospital (RCH) demonstration program.

The attached detailed comments on the proposed changes expand on the points raised above and also on several other important parts of the rule.

The AHA appreciates the opportunity to comment. If you have questions please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273.

Sincerely,

Rick Pollack
Executive Vice President

Attachment

American Hospital Association

Attachment
OPPS Comment Letter
September 16, 2005

Detailed Comments on the Proposed Rule for the 2006 Outpatient Prospective Payment System

APC RELATIVE WEIGHTS

Current law requires that the Centers for Medicare & Medicaid Services (CMS) review and revise the relative payment weights for ambulatory payment classifications (APC) at least annually. The American Hospital Association (AHA) continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates as this information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the August 2000 implementation of the outpatient prospective payment system (OPPS), payment rates for specific APCs have fluctuated dramatically. For 2006, the proposed rates continue to show significant volatility for several reasons.

First, in the proposed rule, CMS uses the most recent claims data for outpatient services to set 2006 weights or rates, using approximately 49 million whole claims for hospital outpatient department services furnished during calendar year 2004 to create 81 million single records. **The AHA continues to support the use of the most recent claims and cost report data to set the 2006 payment weights and rates.**

Second, CMS continues its efforts to include more claims data in the calculation of the APC payment rates, especially those "multiple procedure claims" that contain charges for more than one service or procedure. CMS is proposing to expand the number of Healthcare Common Procedure Coding System (HCPCS) codes it bypasses on a claim – from 383 in 2005 to 404 in 2006 – so that "pseudo" single-procedure claims are created. This list of bypassed codes was developed using an empirical approach established in 2005 and described in the rule. CMS also proposes to continue using "date of service matching" – in which charges are attributed to separately payable HCPCS codes based on the code's date of service – as a tool for creation of "pseudo" single claims. **In general, the AHA continues to support the use of multi-procedure claims, as we believe that these data improve hospital cost estimates. The AHA supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures. We also continue to support the use of "date of service matching" in developing the 2006 outpatient rates.**

The AHA is concerned, however, that while the proposed rule provides a detailed description of the methodology used to calculate the APC weights, it does not provide adequate information for hospitals to evaluate the impact of each of the proposed policy changes independently or in combination. Questions such as, "What would the weights be without the changes?" and "How much of the volatility in the weights is due to the changes?" cannot be answered due to this lack of data. **The AHA requests that CMS**

provide a public use file that shows the impact of each individual proposed change in methodology so that health care providers can review the file to determine how the changes would affect their own operations, and provide a basis for submitting thoughtful comments to CMS.

In addition, although we understand the empirical criteria used to determine the additional codes to add to the bypass list, we find it puzzling that the bypass list includes only some office visit and consultation services codes. For instance, the list includes HCPCS codes 99213 and 99214, but not 99211, 99212, and 99215. One could speculate that this might be explained, in part, by the continuing lack of consistency across hospitals in the use of the evaluation and management (E/M) codes due to the absence of uniform guidelines for hospital coding of E/M services. **The AHA seeks clarification regarding why only some of the office visit and consultation service E/M codes are included in the bypass list.**

Proposed Changes to Packaged Services: The AHA commends CMS and the APC Panel's Packaging Subcommittee for initiating a process to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. When hospitals provide services described by these "N" status codes alone, there is no way to be reimbursed for the costs of providing these services. **We strongly encourage CMS to continue to work with the APC Panel's Packaging Subcommittee to further review "N" status codes and identify those that should be paid separately.**

PARTIAL HOSPITALIZATION

The AHA is concerned that the proposed 15 percent reduction in the per diem payment rate for partial hospitalization services could dramatically harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. These services already are quite vulnerable, with many programs in recent years closing or limiting the number of patients they can accept.

We share CMS's concern about volatility of the community mental health center (CMHC) data and support the agency's intent to monitor CMHC costs and charges for these services, and work with CMHCs to improve their cost reporting so that payments can be calculated based on better empirical data.

Although the AHA recognizes that CMS made the proposal to avoid at a later time an even more significant reduction in the payment rate for these services, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services. Instead, the AHA recommends that in the final rule for 2006, CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

CONVERSION FACTOR

The AHA assumes that CMS again will follow the practice it has used in previous years of utilizing the same market basket update published in the inpatient PPS final rule for the purposes of the outpatient PPS. In the inpatient final rule for FY 2006, CMS responded to an AHA request and changed the market basket estimation methodology to provide a better estimate of hospitals' cost increases. We assume that this change also will be part of the final outpatient rule.

EXPIRING HOLD HARMLESS PROVISION FOR TRANSITIONAL CORRIDOR PAYMENTS FOR CERTAIN RURAL HOSPITALS

The AHA is concerned about the impact that the expiration of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. The AHA is working with Congress on legislation to permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

RURAL HOSPITAL ADJUSTMENT

In the proposed rule, CMS discusses the study the agency conducted, in compliance with Section 411 of the Medicare Modernization Act (MMA), to determine whether rural hospital outpatient costs exceed urban hospital outpatient costs. CMS noted that it conducted an explanatory regression analysis that included three specific classes of rural hospitals – rural sole community hospitals (SCHs), rural hospitals with fewer than 100 beds that are not rural SCHs, and other rural hospitals. CMS conducted this analysis to determine whether the small difference in costs found between rural versus urban hospitals in the initial regression analysis was uniform across rural hospitals or whether all of the variation was attributable to a specific class of rural hospitals. The results of this explanatory regression analysis led CMS to conclude that rural SCHs are more costly than urban hospitals. Therefore CMS proposes to provide a 6.6 percent payment increase for rural SCHs for 2006.

The AHA is concerned that Table 6 in the proposed rule, which includes the results of this analysis, does not separate the regression results for rural hospitals with 100 or fewer beds that are not rural SCHs. While CMS implies in the preamble that the results for this category of hospitals were not significant, we believe it is important to report the results for these hospitals, as they will be the facilities that will lose their hold-harmless protection in 2006. **Therefore, we urge that in the final rule, CMS either present in Table 6 the regression results for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.**

The AHA also seeks clarification on three issues: (1) Would a SCH located in a rural area, which has been reclassified for wage index purposes into an urban area, be eligible for the SCH adjustment? (2) Would a SCH located in an urban area, which has been reclassified for wage index purposes into a rural area, be eligible for the SCH

adjustment? (3) Would rural SCHs participating in the Rural Community Hospital (RCH) demonstration program be eligible for this adjustment?

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospitals' losses when treating high-cost cases. For 2006, CMS proposes reducing the outlier pool to 1 percent of total outpatient PPS payments. Further, CMS says that the fixed-dollar threshold should be increased by $400, to $1,575, to ensure that estimated 2006 outlier payments would equal 1 percent of total outpatient PPS payments. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,575 more than the APC rate.

While the AHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, we are concerned that CMS has set the thresholds for outliers in this rule too high. The AHA seeks further clarification from CMS regarding how the agency determined that a $400 increase in the fixed-dollar threshold was appropriate and how the $1,575 fixed-dollar threshold was calculated.

In addition, for the past four years, CMS set aside 2 percent of total estimated outpatient PPS payments to fund outlier payments to hospitals. For 2006, CMS is proposing to set aside only 1 percent for outliers. However, CMS does not publicly release in the *Federal Register* or on the CMS Web site data about how much of the outlier set-aside was actually spent in prior years. With the significant changes to outlier policies proposed for 2006, the AHA is concerned that Medicare may not actually spend the outlier target set-aside.

The AHA strongly recommends that in the final rule CMS publish data on actual outlier payments made in 2004 and prior years, that actual outlier payments for 2005 be reported as soon as CMS is able to obtain complete data, and that CMS continue to report this data into the future. If CMS is able to obtain this information on the inpatient side and publicly report it, it should be similarly obtained and reported on the outpatient side. Interested parties should not have to purchase costly databases in order to determine whether these thresholds are being set at the right level. Even if CMS believes that it does not have a statutory mandate to return unspent outlier pool funds to the outpatient PPS system, we believe that CMS has a duty to make appropriate estimates, and we are concerned that CMS cannot set the outlier threshold at an appropriate level if it does not know the actual outlier spending.

In issuing a public accounting of total outlier payments for 2005, CMS will need to take into consideration the implications of an error that occurred in identifying services that qualified for outlier payments. CMS incorrectly set the outlier threshold too high in the 2005 fiscal intermediary system, which resulted in underpayment for outliers. Providers were requested to identify and re-bill those claims that should have received outlier

payments. These additional outlier payments should be considered in its calculation of actual outlier expenditures for 2005.

NEW TECHNOLOGY

The AHA supports CMS's proposal to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA's) CPT Editorial Panel before CMS accepts a New Technology APC application for review.

As we have noted in prior comment letters and verbally before the APC Advisory Panel, the proliferation of G-codes and C-codes and their potentially overlapping descriptions with CPT codes is confusing and burdensome for hospital coders. This confusion often has resulted in incorrect coding and unreliable data available for rate setting. Requiring that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G- or C-codes. HCPCS level II G- and C-codes generally are not accepted by payers other than Medicare, thus requiring hospitals to have two different codes to report the same procedure, depending on the payer. This new process will reduce the duplication of codes so that it will start the process correctly via CPT, rather than with a New Technology assignment and no way to report the procedure. While we understand that circumstances may exist when a G- or C-code still will be required, having a CPT code available for new technology will simplify the billing and coding process for hospitals because one set of codes (i.e. CPT) will be used as much as possible for all payers.

Device manufacturers may not be planning ahead and applying for CPT codes for a variety of reasons, including fear of application denial. In any event, the CPT process involves a more rigorous process than level II HCPCS codes and includes the opportunity for input from the physician specialty societies. Without support from the physician specialties that would embrace the new technology, it is doubtful that the new technology will achieve acceptance from the medical community. Input from the physician community also ensures that the code descriptor selected for new technology procedures will be as close as possible to the terminology that physicians will use to document these services. This in turn will reduce the confusion in determining proper code selection.

HYPERBARIC OXYGEN

The AHA supports CMS's decision to no longer use the respiratory therapy cost-to-charge ratio (CCR) for purposes of calculating the median cost for hyperbaric oxygen therapy (HBOT), and instead use the hospital's overall CCR. Since some hospitals, though, currently report HBOT costs on a separate line on their cost report, the AHA would recommend that in 2006, CMS should calculate the median rate for HBOT using the HBOT CCR for hospitals that report separately. If hospitals do not separately report HBOT, then the overall hospital CCR would be used. In order to develop more accurate rates for HBOT in the future, CMS should encourage hospitals to report the HBOT costs on a separate HBOT line on their cost report. This should not be administratively

difficult for hospitals because HBOT revenues already are captured in a specific separate revenue code, and would involve only a change in where costs for HBOT are reported on the cost report.

NON-PASS-THROUGHS

The MMA requires that in 2006, payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to any adjustment for overhead costs. In the proposed rule, CMS evaluates three alternatives for setting 2006 payment rates for these drugs: (1) average and median purchase price data for drugs purchased from July 1, 2003 to June 30, 2004 derived from a General Accountability Office survey of 1,157 hospitals; (2) the average sales price (ASP) data from the fourth quarter of 2004; and (3) mean and median costs derived from the 2004 hospital claims data. After considering the merits and weaknesses of each approach, CMS proposes to pay ASP+6 percent for separately payable drugs and biologicals in 2006.

In general, the AHA supports this proposal and agrees that paying for drugs at ASP+6 percent appears to be the best available estimate of average acquisition cost. This also has the additional benefit of providing for consistent payment rates across the hospital outpatient PPS and the physician fee schedule payment systems. Finally, given the inflation in drug prices over time, we believe that the ability to update ASP rates on a quarterly basis also is a key advantage of this proposal. However, the proposal to pay at ASP+6 percent will result in significant reductions in payments for some separately payable drugs and biologicals.

Therefore, the AHA supports the APC Panel's recommendation that CMS carefully track the drug codes to be paid at ASP+6 percent, with a particular focus on drugs with rates that would fall significantly in 2006. We are concerned that steep drops in payments for certain drugs and biologicals could have implications on manufacturer production levels of these drugs and hurt patient access to some drug therapies. If CMS obtains evidence that access to certain drug therapies would be threatened due to payment rate decreases, then it should consider freezing payments or otherwise limiting decline in payments for these products.

Pharmacy overhead and drug handling adjustment: In the proposed rule, CMS took into consideration the Medicare Payment Advisory Commission (MedPAC) recommendations on how to adjust the APC rates for separately payable drugs to account for pharmacy overhead and drug handling costs. To address this, CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories. This will differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy C-code for overhead costs associated with the administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides in preparing to administer the product. Since CMS does not have separate hospital charge data on pharmacy overhead, the agency proposes for 2006 to pay for these costs based on 2 percent of the ASP. This would result in overall drug payments, including the drug itself and the associated handling

payment, of ASP+8 percent, which CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

The AHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We are concerned, however, that the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. As noted above, we recommend that CMS consider freezing payments in 2006 for those drugs whose payments would decline significantly from the 2005 rates, particularly for drugs that may have especially complex and costly handling requirements. In the future, CMS should work with hospital and pharmacy stakeholders to establish differential add-on payments for drug handling costs for a wide variety of drug handling categories.

The AHA strongly opposes CMS' proposal requiring hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals, and utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome and difficult for hospitals to implement.

There are many complex issues and administratively burdensome aspects to adopting CMS' proposal for charging for drug handling through the use of these new C-codes. The most important is that, if implemented, this policy would seem to be inconsistent with the requirement that Medicare providers maintain uniform charges for all payers (see 70 *Federal Register* 42693). Given this, it is impossible to charge Medicare a rate that does not reflect handling costs, and charge other payers for the same drug a higher rate that does reflect handling costs. This simply could not be done. Even assuming that hospitals could provide differential charges, other concerns remain:

- Hospitals would have to evaluate the normal mark-up formula for all pharmacy items and deduct the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug. This would be an extremely complex and time-consuming process.
- For each separately payable drug, hospitals would need to assign the handling charge to one of CMS's proposed new drug handling C-codes. These C-codes are only recognized by and acceptable to Medicare, but not to other payers. Hospitals therefore would have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims, but bill them as a single line item for other payers. Setting aside the concern raised above about violating the Medicare requirement for uniform charges, this also introduces another level of complexity and burden.
- Confusion exists about how the drug handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient. Would the hospital report a single C-code for handling costs in this case or multiple C-

codes? Confusion around how to charge could result in incorrect data, which would make it difficult to establish appropriate future payment rates for these services.

- Drug pricing is generated through a pharmacy charging system often located outside the hospital's normal charging system, and may not be able to accommodate CMS' proposed C-codes.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, it is unclear how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

The AHA also is aware that the APC Panel, based on testimony provided by a number of organizations representing drug manufacturers and others, has proposed that CMS expand the application of its proposed drug handling coding and payment methodology to drugs that are packaged into other APCs. **The AHA strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes.** In addition, hospitals generally do not provide detailed billing for drugs that are not separately paid, meaning that hospitals do not separately assign HCPCS C-codes or J-codes for these drugs. More importantly, not all drugs have C-codes or J-codes. Creating new codes for all drugs would be a significant burden. It would therefore be extremely difficult for hospitals to bill the right drug handling C-code for packaged drugs. Further, many hospitals that have adopted a paperless billing system also use an imaging system to generate a bill for a patient. Given the large volume of drugs used in hospital outpatient departments, expanding the drug handling coding requirements to all these drugs, regardless of their packaging status, would dramatically increase hospital administrative costs associated with this already misguided proposal.

The AHA strongly recommends that CMS *not* implement the proposed drug handling C-codes in 2006. Instead, we recommend that CMS work with stakeholder groups to collect additional data, and develop alternative and simpler solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs. Such an approach should incorporate the payments for drug handling directly into the payment rate for the drug itself, rather than requiring separate coding systems. The AHA would be pleased to convene a group of member hospitals to work with CMS and with the APC Advisory Panel to discuss possible alternatives.

If CMS decides to implement this burdensome drug handling C-codes policy, then AHA strongly suggests that CMS provide a grace period of no less than 6 months after implementation of the 2006 outpatient PPS (June 1, 2006) so that hospitals can create the new charging system, make system changes and educate pharmacy staff, hospital finance staff, and coders on the required use of the drug handling "C" codes.

DRUG ADMINISTRATION

The AHA continues to support CMS' proposal to use CPT codes to bill for drug administration services provided in the hospital outpatient department. Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for Medicare and non-Medicare payers. We understand that under the proposed methodology, payment for services within the same APC would be collapsed by the outpatient code editor (OCE) into a single per-visit APC payment – just as it currently does – until 2005 claims data become available, when CMS will provide further refinement and recognize resources associated with drug administrations that last several hours.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes. For example, clarification will be needed regarding the following:

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting—especially for non-oncology providers of infusion and injection services, since they often cross departments.
- Definitions of what constitutes an "initial" vs. subsequent infusion vs. concurrent infusion.
- Definition of "hydration" and how it is different from a hydration that is given for therapeutic reasons. In other words, a therapeutic infusion can be hydration.
- How should infusions or titrations be reported? Many times they are established with a documented start time and administered via pump. As such, many infusions are maintained by equipment function rather than manual intervention. In these cases, a nurse may be aware of the start time of an infusion and may document it. It is unlikely, though, that the stop time will be documented.

The AHA welcomes the opportunity to work with CMS on coding education, as well as on the development of appropriate future rates for drug administration in hospital outpatient departments.

E/M SERVICES

Since the implementation of the outpatient PPS, hospitals have coded clinic and emergency department (ED) visits using the same CPT code as physicians. CMS has recognized that existing E/M codes correspond to different levels of physician effort but do not adequately describe non-physician resources. Although hospitals were anticipating that CMS would propose a national, uniform E/M coding system in 2003, the agency chose not to do so. As a result, in 2003 the AHA and the American Health Information Management Association convened an independent panel of experts to develop a set of coding guidelines for CMS.

Specifically, the panel recommended that CMS should:

1. Make payment for emergency department and clinic visits based on four levels of care.

2. Create HCPCS codes to describe these levels of care as follows:
   - Gxxx1 - Level 1 Emergency Visit
   - Gxxx2 - Level 2 Emergency Visit
   - Gxxx3 - Level 3 Emergency Visit
   - Gxxx4 - Critical Care provided in the Emergency Department
   - Gxxx5 - Level 1 Clinic Visit
   - Gxxx6 - Level 2 Clinic Visit
   - Gxxx7 - Level 3 Clinic Visit
   - Gxxx8 - Critical Care provided in the Clinic
3. Replace all the HCPCS currently in APCs 600, 601, 602, 610, 611, 612, and 620 with GXXX1 through GXXX8.
4. Crosswalk payments from GXXX1 to APC 610, GXXX2 to APC 611, etc.

In the 2004 and 2005 OPPS rules, CMS stated it would consider national coding guidelines recommended by the panel, and planned to post for public comment the proposed guidelines on the outpatient PPS Web site. CMS also proposed to implement new E/M codes only when it could also implement guidelines for their use. This guidance would be issued after ample opportunity for public comment, systems change and provider education.

The AHA is disappointed that the 2006 proposed rule fails to include national guidelines for facility E/M reporting. While we applaud CMS as the agency continues to develop and test the new codes, hospitals still are without a standard methodology for reporting E/M services. This lack of uniformity not only puts hospitals at compliance risk for multiple interpretations of the level of service that should be coded and billed, but also affects CMS' ability to gather consistent, meaningful data on services provided in the emergency department and hospital clinics. This is especially important because CMS uses the mid-level clinic visit (APC 601) as the anchor for establishing the relative weights within the outpatient PPS, and, due to a lack of national coding guidelines, there is no agreement on what a mid-level clinic visit encompasses. We believe that the E/M coding recommendations made by the independent panel will adequately meet hospitals' needs.

BLOOD AND BLOOD PRODUCTS

CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood

product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition costs, most notably for leukocyte-reduced red blood cells. With the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, the AHA recommends that CMS set 2006 rates at *the greater of*: the simulated medians calculated using the 2004 claims data; or the 2005 APC payment medians for these products.

The AHA also commends CMS for issuing in March 2005 comprehensive and clear billing guidelines for blood and blood products, addressing issues such as the blood deductible and differences between donor and non-donor states. This document was well received by hospitals, and it should help clear up much of the confusion regarding the correct way to code and bill for blood and blood products. The AHA will continue to work with and educate our member hospitals, using CMS' blood billing guidelines about appropriate blood coding and billing practices.

OBSERVATION SERVICES

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain and asthma. To reduce the administrative burden on hospitals attempting to differentiate between packaged and separately payable observation services, CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). CMS would shift determination of whether observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

The AHA supports the concept of allowing the OCE logic to determine whether services are separately payable. This will result in a simpler and less burdensome process for ensuring payment for covered outpatient observation services. As we stated in the hospital outpatient PPS in 2003, the existing G codes for observation services, with their long, complex descriptors that encompass all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are very pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently to make the HCPCS code GYYYY unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center)

revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through the ED or urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission, and pay accordingly.

Further, the AHA seeks clarification on the reference to inpatient status on page 42743 in the proposed rule that states "That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to 'observation status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient." We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

INPATIENT PROCEDURES

CMS proposes to remove 25 codes from the "inpatient only" list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The AHA continues to urge CMS to eliminate the "inpatient only" list. Physicians, not hospitals, determine where procedures can be performed safely, as well as whether a patient's condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, then under current rules the hospital is penalized if that procedure happens to be on the "inpatient only" list.

If the "inpatient only" list is not eliminated for 2006, CMS should consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the "inpatient only" list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

ANCILLARY OUTPATIENT SERVICES

In the proposed rule, CMS expresses concern about the increase in the volume of hospital claims that are billed with the –CA modifier from 2003-2004, growing from 18 to 300 claims over that one year. This modifier was initially used in 2003 to address situations where a procedure on the "inpatient only" list must be performed to resuscitate or stabilize a patient in a hospital outpatient department with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient. In addition, CMS states that a clinical review of the claims reported using this modifier support their concerns regarding the increased modifier volume and hospitals' possible incorrect use of the modifier for services that do not meet the payment conditions CMS established.

The AHA agrees that the –CA modifier should be used only in rare circumstances. It is unclear why CMS has seen such a substantial increase in the use of the –CA modifier. It could be that hospitals are using the modifier incorrectly, or that, because it is a relatively new modifier, hospitals were only recently aware of it. In addition, there may be circumstances to explain why few of the claims also include a clinic or emergency department visit on the same date of service as the procedure appended with a –CA modifier. For example, a Medicare beneficiary arrives for a scheduled procedure and, due to complications, the physician finds it necessary to provide a service that they had not otherwise intended to perform in an outpatient setting, and the patient dies prior to admission.

The AHA believes that the –CA modifier policy supports an important function for hospitals and should be preserved. However, it appears that hospitals would benefit from additional education on the appropriate use of the –CA modifier. **In collaboration with CMS, the AHA will provide further education to hospitals through its Coding Clinic publication.** In addition, we support CMS' continuing to closely monitor hospital use of this modifier.

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

CMS proposes reducing payment when multiple imaging services are provided on the same day. In accordance with a MedPAC recommendation CMS proposes to make full payment for the highest paid imaging service and pay 50 percent of the APC payment rate for every additional procedure within the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area.

The AHA opposes implementation of this policy without better justification and more substantial, supporting hospital-based data. In developing this policy, CMS did not examine hospital cost data. Rather, the agency relied on Medicare physician fee schedule practice expense data to determine the level of the discount. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies, if they exist.

Furthermore, CMS uses different methods to set payments in physician offices and hospital outpatient departments. The physician fee schedules are based on expert opinion of the resources required to perform different services while the outpatient rates are set based on hospital cost data. Hospitals conduct imaging procedures in unique circumstances not found in physician offices, such as in EDs and urgent care circumstances. **We urge CMS to conduct analyses using hospital data before implementing this policy.**

In addition, hospital cost data already may reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures. CMS determines the median cost for outpatient services by multiplying the charges on the

claim by the appropriate hospital department's cost-to-charge ratio (CCR). And while costs may be lower when multiple imaging studies are performed during the same session, most hospitals do not reduce their charges when more than one imaging service is performed in the same encounter. The hospital's CCR would therefore be lower than it should be because the denominator (charges) is higher than it otherwise would be if the hospital had charged less for the subsequent imaging studies. This results in a cost determination at the individual service level that is too low for single imaging studies, and too high for subsequent imaging studies. Because hospitals do both single and multiple imaging studies, the overall payments may be appropriate as they currently are calculated. **However, CMS's proposal to discount payments for subsequent imaging studies performed during the same encounter would underpay for both single procedures and for the highest rate APC when multiple imaging procedures are performed and reduce payment for other imaging services provided.**

We are also concerned with how this policy will be implemented and the lack of detail provided in the proposed rule, such as defining "the same session." During a suite of tests or an emergency stay, a patient may have an imaging procedure done in the morning, followed by medical review or other tests that indicate the need for a procedure from the same "family" later in the day. In this case, the tests would not be performed at the same time, or perhaps even in the same part of the hospital, and would be incorrectly subject to the discount. The APC advisory panel rejected the use of modifier 59 (separate procedure) for this purpose as too burdensome because it would require hospitals to track patients through the course of a day.

Finally, the proposed rule states that this policy will be budget neutral. However, no detail is provided on how the impact of the multiple imaging procedures discount was estimated or how the budget neutrality factor was adjusted to account for this. What share of imaging procedures did CMS estimate to be multiple imaging procedures? How were they defined? Will CMS analyze the data later to see if the estimates were correct?

In conclusion, the AHA agrees with the APC advisory panel recommendation that this policy should not be implemented without additional analysis and better substantiation.

INTERRUPTED PROCEDURES

CMS proposed to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted for clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs actually may increase, not decrease, as the clinical team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, many of the hospital's costs already will have been incurred. For example, the operating room will have been occupied during the start of

the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and either will be disposed or be reprocessed at additional cost.

Before CMS reduces payments for procedures billed using these modifiers, evidence must support both the need for and the level of those reductions.

PHYSICIAN OVERSIGHT OF NONPHYSICIAN PRACTITIONERS

The AHA supports CMS's proposal to defer to state law regarding the need for physicians to review and sign the medical records for outpatients cared for by nonphysician practitioners in critical access hospitals (CAHs). However, we also recommend that CMS extend the application of this policy to physician review of inpatient records for patients cared for by nonphysician practitioners. If state law permits these practitioners to practice independently, CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that state laws providing independent practice authority generate sufficient control and oversight of these nonphysician practitioners, and we do not believe that nonphysician practitioners reduce quality of care

The AHA also supports the additional flexibility CMS adds under this proposed policy for those states that do not allow for independent practice of nonphysician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

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CCRIs

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BY HAND DELIVERY

Dr. Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
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Dear Dr. McClellan:

GlaxoSmithKline (GSK) has offered comments in support of the proposed rule with regards to the use of the cost to charge ratio as applied to payments for radiopharmaceuticals in the hospital outpatient setting. This methodology is also suggested for other items such as devices. The purposes of these additional comments are to (1) further clarify that the CMS proposal concerning HOPPS reimbursement based on the cost to charge ratio for radiopharmaceuticals should be implemented without modification and (2) encourage CMS to consider increases in reimbursement to hospitals for pharmaceutical handling costs.

GSK reiterates our support for the proposed cost to charge ratio based methodology but are aware that some manufacturers are concerned that hospitals may not receive sufficient reimbursement if they do not submit accurate charges. To preserve reimbursement for their products and to insulate themselves against inaccurate charges as reported by hospitals, these manufacturers have suggested that there be a reimbursement floor for items that are reimbursed according to the cost to charge ratio. One suggestion is that the floor be a percentage of 2005 HOPPS reimbursement. Basically, if the application of the cost to charge ratio to the hospital's stated charges results in reimbursement below that floor, then reimbursement would equal that floor. GSK understands the concerns of these manufacturers but does not believe that CMS should implement a floor in addition to the implementation of a CCR approach.

We understand that there are variations in the cost data reported by hospitals in their charge reports. In some cases, some people have believed that this has led to inappropriate Medicare reimbursement for a variety of pharmaceutical and other products in previous HOPPS approaches. GSK believes that it is important that hospitals, as well as manufacturers, be encouraged to report accurately to CMS and that setting an artificial reimbursement floor reduces hospitals' incentive to do so. We are concerned that there will continue to be concerns about hospital reported data and

that if these data were used as a basis for a permanent reimbursement methodology, that methodology will be vulnerable to criticism because of the potential inaccuracies in the hospital reported data. GSK believes that hospitals should have the incentive to provide accurate information and not be given the opportunity, through a virtual guarantee, to opt out.

Further, because the proposed rule already would provide hospitals with an opportunity to report charges accurately for each claim, GSK strongly believes that there is no need for CMS to provide any additional safeguards to ensure sufficient reimbursement. Those safeguards are already embodied in the proposed methodology. If the proposal were to be implemented, hospitals would already have the ability to receive appropriate reimbursement by reporting appropriate charges in their claim.

In addition to our suggestions regarding radiopharmaceuticals, GSK would also like to comment on the proposal to provide reimbursement to hospitals for their handling of pharmaceuticals. We appreciate that CMS has identified that hospitals do incur handling costs but we have heard from hospitals that their actual costs are in excess of the 2% of ASP as included in the proposed rule. GSK has no independent knowledge of hospital actual costs but the concerns voiced by hospitals are voiced consistently and they appear to be consistent with other, third party documentation of hospital costs. Accordingly, GSK is supportive of the hospitals' concerns and encourages CMS to consider an increase in reimbursement for hosptial handling costs for pharmaceuticals.

Finally, the proposed rule contains some discussion regarding a long term reimbursement methodology of radiopharmaceuticals. That long term methodology could be implemented in 2007 or thereafter. At this time, GSK has no opinion regarding reimbursement methodologies for diagnostic radiopharmaceuticals but does believe that it may be appropriate to reimburse hospitals for therapeutic radioimmunotherapies based on the same calculation for ASP as used for physician administered pharmaceuticals. If an ASP is used for radioimmunotherapies, GSK would encourage the development of reimbursement codes for the costs of compounding the products, as these costs are necessary and differ from the costs of other physician administered drugs.

Thank you for the opportunity to comment on this proposed rule on hospital outpatient reimbursement. Please feel free to contact us with any questions or requests for additional information.

Sincerely,

Barry Gershon
Director, Public Policy and Advocacy

Pymt DBR

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September 12, 2005

BY HAND DELIVERY

Mark McClellan, M.D., Ph.D.
Administrator of Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Comments on Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

On behalf of Astellas Pharma US, Inc. ("Astellas"), I am submitting the following comments in response to the proposed rule for the hospital outpatient prospective payment system (HOPPS) for calendar year (CY) 2006 published in the Federal Register on July 25, 2005 (70 Fed. Reg. 42674) - the "Proposed Rule." Our comments are directed principally to the proposal to pay for all separately payable drugs using the same average sales price plus 6% rate that applies to drugs furnished in the physician office setting. Astellas supports this proposal and urges the Centers for Medicare & Medicaid Services ("CMS") to finalize this proposal. In addition, we also support the agency's decision to pay an additional amount to hospitals to ensure that they are properly paid for the handling costs incurred in connection with drugs and biologicals.[1]

Astellas was launched in April 2005 as the result of a merger of two of Japan's largest pharmaceutical companies – Yamanouchi and Fujisawa. It blends the strengths, talents, and resources of these companies into one entity. In the United States, Astellas focuses on five key therapeutic areas: cardiology, dermatology, immunology, infectious disease, and urology. The hospital outpatient department is a site of service in which many of our current products are provided to Medicare beneficiaries and we anticipate that will be the case with our future products as well. Thus, we have a keen interest in ensuring the propriety of the mechanism for paying for drugs under HOPPS.

To that end, we were pleased to see that CMS has proposed "to pay for all separately payable drugs and biologicals at the payment rates effective in the physician office setting as determined using the manufacturer's average sales price (ASP) methodology." 70 Fed. Reg. at 42756. Astellas believes that this is an appropriate mechanism for determining payment rates for drugs under HOPPS, considerably more so than the median cost methodology that has been

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[1] Given the scope of our comments, the sole issue identifier pertinent to this letter is "NonPass-Throughs."

astellas

used to pay for separately billable drugs over the past few years. The agency's proposed methodology should ensure that beneficiaries have continued access to our products in the hospital outpatient setting. Therefore, we recommend that CMS finalize this proposal.

Astellas also commends CMS on its recognition that a separate payment should be made to reimburse hospitals for the costs they incur in handling drugs and biologicals. Noting that it lacks data on these handling costs, CMS proposes to reimburse hospitals an additional 2% of ASP for such costs. 70 Fed. Reg. at 42730. We understand that some of our hospital customers believe this separate handling cost payment to be inadequate and we encourage CMS to consider carefully any available evidence in finalizing the level of this separate payment amount to be sure that it fairly pays hospitals for the very tangible handling costs they incur.

On behalf of Astellas, I appreciate your consideration of this issue. If I can provide any additional assistance, please call me at (847) 405-1606.

Sincerely,

Jorja K. Sturek
Director of Reimbursement Strategy
Astellas Pharma US, Inc.

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2005 SEP 15 P 2:28

September 14, 2005

CCBIS
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Mark McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1501-P
Room 445-G, HHH Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System
Proposed Rule (CMS-1501-P)
Update for Calendar Year 2006

Dear Dr. McClellan:

On behalf of Laserscope, I want to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Notice of Proposed Rulemaking ("NPRM") regarding the Hospital Outpatient Prospective Payment System for 2006 ("HOPD PPS")[1] as it pertains to Medicare payment for GreenLight PVP, a New Technology used to treat benign prostatic hyperplasia through photo-selective vaporization of the prostate ("GreenLight PVP"). Moreover, I want to thank the staff members of the Center for Medicare Management who have given their time and attention to understand and respond to the reimbursement problems impacting access to this state-of-the-art treatment.

The GreenLight Laser was cleared by the FDA in 2001 for the treatment of BPH. It is the only technology available today that uses the 532nm or "green" wavelength as an energy source, and as explained in greater detail below, this unique biophysical property is of tremendous clinical significance. In fact, it sets treatment with the GreenLight apart from any other laser technology on the market.[2]

532nm light has the biophysical property of having a substantial absorption affinity to oxyhemoglobin in tissue and simultaneously has virtually no absorption in water or sterile saline. This unique combination of absorption characteristics, known as selective photothermolysis, results in the vaporization of blood vessels and tissue with virtually no absorption in saline irrigant making 532nm a unique and ideal tool for

[1] 70 Fed. Reg. 42674 (July 25, 2005).
[2] R. Rox Anderson and John A. Parrish, *Selective Photothermolysis: Precise Miscrosurgery by Selective Absorption of Pulsed Radiation*, 220 Science 524 (1983).

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performing virtually bloodless surgical removal of tissues, especially obstructive prostate tissue, with no practical operating time limitation. Other laser technologies, such as Holmium or Nd:YAG lasers, do not use a similar energy source or wavelength, and, therefore, are not capable of producing the same physiologic result or clinical outcomes. GreenLight PVP is the only treatment clinically proven to safely and effectively remove obstructive prostate tissue in the hematologically impaired and high risk patient. In fact, the Greenlight PVP has not been clinically contraindicated in virtually any patient. Men on anticoagulation therapy have been treated using PVP without being removed from their blood thinning medication.[3] Thus, treatment of BPH using GreenLight PVP is safer in men with cardiac or other conditions that require them to remain on what could be life-saving blood thinning medications.[4]

A new HCPCS code, C9713, was created by CMS to describe the Greenlight PVP procedure. C9713 was placed in a New Technology APC, APC 1525, because CMS properly recognized that it was both a "truly new service"[5] and that it is different from other laser treatments for prostate enlargement. This New Technology APC went into effect in April2004. (CMS Transmittal 132, Publication 100-04).

The assignment of Greenlight PVP to a new technology APC relieved, at least temporarily, one prong of a critical reimbursement barrier to Medicare beneficiary access to GreenLight PVP – the considerable underpayment of the facility costs incurred by hospitals offering this new outpatient procedure. Indeed, the assignment of GreenLight PVP to a new technology code under the HOPD PPS has made it possible for hospitals to undertake the capital expense to offer GreenLight PVP.

CMS's proposal to assign C9713 to APC 0429, Level V Cystourethroscopy and other Genitourinary procedures, which has a payment rate of $2500, is a $1250, or 33%, reduction in payment. Respectfully, to make such a dramatic reduction based upon less than 9 months of claims data is inappropriate.

I. The data is insufficient to support the reassignment of HCPCS C9713 to a clinically appropriate APC

CMS policy requires it to have sufficient data to support the reassignment of a service from a new technology APC to a clinically appropriate APC. This requirement is essential if CMS is to pay fairly for new technology services. Laserscope believes that CMS does not have sufficient data to justify moving C9713 to a clinical APC and therefore did not follow its own policy in the case of PVP. We note that even though

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[3] A.E. Te, *The Development of Laser Prostatectomy*, 93 BJU Int. 262 (2004); R.S. Malek, K. Nahen, *Laser Treatment of Obstructive BPH – Problems and Progress*, Contemp Urol. 37 (2004); O. Reich, et al., *High Power (80W) potassium-titanyl-phosphate vaporization of the prostate in 66 high risk patients,* J Urol. 173 (2005).

[4] Medicare also benefits because it avoids the additional expense associated with the inpatient hospital stay required to re-establish the patient's anticoagulation therapy post procedure.

[5] CMS has stated that a "truly new service" is one that cannot be appropriately described by existing HCPCS codes and that a new HCPCS code needs to be established in order to describe the new procedure. 66 Fed. Reg. 59899.

CMS no longer requires retention of a service in a new technology APC for two to three years prior to moving the service to a clinical APC, CMS continues to consider two to three years the most appropriate period of time for accurate reporting.[6] A data collection period of less than two years is very unusual; in fact CMS has stated that it needs a full year of available claims data so that a sufficient amount of data is collected for review.[7]

In order to support its belief, Laserscope engaged The Moran Company to analyze the 2004 OPPS data for CPT codes 52647, 52648, and C9713. The results of this analysis show that the claims data for 2004 are completely unreliable and should not be the basis for a decision to change the payment rate for PVP (i.e., C9713).

A. Data Collection Period was Unusually Brief

In the case of PVP, the data collection period for C9713 was less than nine months. Although the implementation date of C9713 was April 1, 2004, CMS transmittal 132, Publication 100-04 was not published and sent to contractors until March 30, 2004 – only two days before the code's effective date. Mid-year coding changes are problematic for hospitals in any event; however, in the case of C9713, hospitals could not possibly have added C9713 to their chargemasters, educated their coding staff on how to properly use the code, established an appropriate charge for PVP, and begun to bill for C9713 until well after April 1, 2004. Moreover, many of the PVP procedures performed in November and December 2004 probably were not submitted to CMS contractors until January 2005 and therefore are not captured in the December claims data.

Thus as set forth below, the sample of data being relied upon by CMS to move C9713 into a clinical APC not only fails to satisfy the agency's typical minimum collection period of two to three years, but it likely is comprised of less than nine months of data that includes reporting of procedures other than PVP.

Specifically, CMS typically publishes its quarterly transmittals several weeks prior to the effective date so that contractors have sufficient time to reset their systems to accept the new codes and hospitals and providers have time to become familiar with the new codes. A mere two days is not enough lead time for hospitals to update cost information, charge masters and coding instructions to reflect new technology HCPCS codes. In fact, the 2004 claims data suggest that nine months was an insufficient period of time. Out of the 167 hospitals known to have and use the Greenlight laser, only 28 hospitals (or 17%) submitted claims using the new technology code. Because of these coding errors, the vast majority of the claims for PVP procedures performed had to have been submitted incorrectly. As a result, the cost and charge data used to determine the median payment rate for the APC is based on input from only 28 hospitals which performed PVP; more importantly, all the other hospitals reporting C9713 were reporting a service other than PVP, hardly a sample that could be considered to represent accurate coding.

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[6] 69 Fed. Reg. 65715.
[7] 66 Fed. Reg. 59902.

Second, many of the PVP procedures performed in December 2004 probably are not captured in the December claims data. Claims for services provided during the month, especially in late December, most likely were not submitted until January because of the December holidays. The exclusion of these claims suggests that CMS had even less than nine months of claims data to consider. Between the delay in issuing Program Transmittal 132, and the probable hold over of December claims to January, it is likely that CMS had at best seven months of data upon which to make such an important decision.

B. Aggregate Data is Unreliable based on the Universe of Procedures

A robust claims sample is necessary to ensure that the reimbursement rate accurately reflects the resources expended in providing the service. CMS held off reassigning radiation oncology and PET services to clinically appropriate APCs until it had a data pool of over 225,000 claims, of which 95% were single claims, and data pool of over 61,492 claims, of which were 91% single claims, respectively.[8] Yet, in the case of PVP, the agency is proposing to set a reimbursement rate on the basis of 1,276 single procedure claims, many of which represent inaccurate coding. Furthermore, as discussed below, even hospitals that were performing PVP appeared to have assigned incorrect charges and improperly reported C9713 due to a lack of understanding of the code. Even if all the claims did represent PVP they would account for only 13% of the 10,000 PVP procedures that were performed from April 2004 through the end of that year. This claims data is not representative when compared to the universe of PVP procedures.

The claims data sample for PVP procedures is similar to the sample of claims for angiography of the aorta (CPT 75635 and APC 0662) that CMS decided should not be reassigned to a new technology APC because the service was relatively new, the claims data sample consisted of 1,300 procedures and the data costs may have been understated.[9] The same rationale applies to the PVP procedures. PVP still is new, only 1,276 claims were available to CMS, and as discussed below, the costs data considerably understates the cost of performing PVP procedures.

C. Median Costs/Charges Understate the Resources Expended to Perform PVP Procedures

The median costs must accurately reflect the resources expended to perform PVP procedures to justify the assignment to a clinically appropriate APC. A fair reimbursement rate simply cannot be established when the underlying cost data used to set the rate significantly understates the resources expended to perform a procedure. Historically, when the costs reported do not accurately capture the entire cost of the procedure, CMS has determined that the claims data is not sufficient to support the reassignment to a clinically appropriate APC.[10]

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[8] 69 Fed. Reg. 65715, 65717.
[9] 68 Fed. Reg. 63415.
[10] Id.

This is precisely the case with the claims data for C9713, as the median costs understate the resources expended to perform PVP procedures. We suspect that this failure is due to the fact that hospitals did not accurately report the cost of performing PVP procedures. This is reflected in the ambiguity of the two existing laser CPT codes, 52647 and 52648, and the considerable coding errors that were made in billing either of these codes. Many of the coding companion publications, including the American Medical Association's (AMA) 2005 Healthcare Common Procedure Coding System and the Ingenix® 2005 Urology/Nephrology coding and reimbursement handbook, contained conflicting information in regard to the HCPCS assignment. For example the AMA's HCPCS coding companion describes C9713 as: non-contact laser vaporization of prostate, yet it recommends using CPT 52647 as a crosswalk, which is the described as: non-contact laser coagulation of prostate. Hence coagulation and vaporization are erroneously cross walked together. In the Ingenix® 2005 reimbursement coding companion it states under CPT 52647 and 52648, "no HCPCS level II codes apply". With these kinds of simple publication errors it is not difficult to understand the significant errors in the CMS cost data. Consequently, it is doubtful, given the small fraction of hospitals that coded for PVP correctly, that many hospitals made appropriate chargemaster updates. Therefore, it is unfair to penalize hospitals and providers for errors that were prevalent on a national scale, and that culminated into the collection of a sample of claims that were not indicative of the true costs of PVP.

In many cases, the costs reported simply would not cover the resources required to perform the procedure. For example, thirty-seven percent (37%) of hospitals reported median costs of $1,000; yet the cost of one disposable fiber, which is used in every PVP procedure, is $895. One thousand dollars certainly cannot be accurate. Thus, just as in the case of angiography of the aorta, CMS should continue the assignment of a new technology APC for PVP procedures.

D. **Procedures were Properly Coded**

The validity of the claims data is dependent on proper coding. The 2004 claims data should not be relied upon for rate-setting because hospitals were not properly coding PVP procedures under C9713. Uncertainty about the proper coding for PVP has existed since PVP first became available to patients. As discussed earlier, the confusion arises from the fact that there are two longstanding urologic laser surgery CPT codes (52647 and 53648) that do not accurately describe PVP. Each code captures some aspects of the PVP procedure, but not the complete procedure. Thus, providers struggled to decide which code was appropriate. Part of the goal of establishing a C code was to create some consistency in the system. Unfortunately this goal was not achieved as evidenced by the fact that 83% of hospitals which performed PVP in 2004 did not use the C code to report the procedure. In fact, a member of the Advisory APC Panel acknowledged at the August 18th meeting that the codes were confusing and admitted to improperly coding PVP procedures in 2004.

It is certainly reasonable to assume that providers need more than nine months to

adapt to a mid-year coding change. Even CMS has stated that two to three years is typically required for providers to review billing instructions, update their chargemasters, and educate their coders.[11] Thus it is quite likely that the 2004 claims data is unreliable because the providers were not aware of the coding change and did not know how to properly bill for the services. The improper coding has distorted the claims data for PVP procedures because hospitals are billing for procedures utilizing the Greenlight laser under older codes and billing for procedures utilizing older laser technologies under the new technology codes.

II. CMS Historically Has Avoided Dramatic Reductions in Reimbursement for Providers

A. CMS Should Retain the Service in a New Technology APC at the Same Reimbursement Rate for at Least One More Year

For the foregoing reasons, CMS's own policy of requiring sufficient data to support the reassignment to a clinically appropriate APC is not satisfied. An equitable reimbursement rate cannot be established when the integrity of the underlying cost and charge data is in question. The service should remain in new technology APC 1525 for another year. This is how CMS has treated other like situations in the past, and the same treatment should be extended to PVP. At minimum, a full calendar year of claims is needed to provide a more accurate picture of the resources expended to perform PVP procedure. Armed with another year of experience, CMS could re-assess the claims data in 2006 to determine whether sufficient data exists to set a fair reimbursement rate for PVP procedures.

B. Assuming that CMS Continues to Believe that a Payment Reduction is Warranted, the Reduction in Payment Should be Limited

Assuming that CMS continues to believe that a payment reduction is warranted, the precipitous drop proposed by CMS should be limited. Similar to the payment reduction floor for device APCs, the reduction to PVP reimbursement should be limited to 15%. The rationale and equities behind the payment reduction floor for device APCs applies equally to PVP procedures. This is especially true with new services and technologies like the Greenlight laser where most of the cost of doing the procedure is related to the cost of disposable supplies (e.g., the laser fiber) and capital equipment. In the case of PVP, hospitals made significant capital outlays to purchase new equipment and to train personnel on how to perform PVP. Hospitals invested in providing the PVP procedures because they expected to be adequately reimbursed for their expenditures. A drastic reduction in reimbursement would be unfair to those hospitals.

CMS has dampened the effect of significant payment reductions associated with the reassignment of services from a new technology APC to a clinically appropriate APC

[11] 69 Fed. Reg. 65715, 65717.

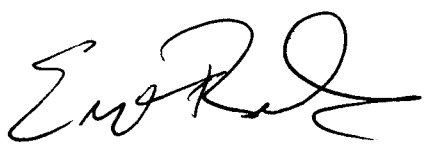
in other instances. For example, when CMS recognized that the cost data for proton beam therapy may have been understated by hospital costs, it set the payment rate based on a 50/50 blend of the median cost of the new technology APC and payment rate for the new technology APC to ensure access to the therapy was not impacted.[12] A similar methodology could be applied to PVP procedures to ensure that providers continue to offer PVP procedures to Medicare beneficiaries.

Limiting the payment reduction to the 15% applied to the device APCs or using a blended rate as described above, results in a payment rate for PVP of approximately $3,250. Therefore, we believe that at the least PVP should be reassigned to APC 1524 for 2006.

* * *

Thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact me.

Respectfully submitted,



Eric Reuter

President and CEO

Laserscope

[12] 69 Fed. Reg. 65720.

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Rural Referral Center
Sole Community Hospital
coalition

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September 14, 2005

BY HAND DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1501–P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, CMS–1501–P, 70 *Fed. Reg.* 42,674 *et seq.* (July 25, 2005).

Dear Sir or Madam:

Please accept these comments regarding proposed changes to the hospital outpatient prospective payment system ("OPPS") and calendar year 2006 payment rates, and specifically the **Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals** and **Rural Hospital Adjustment**, both of which are discussed beginning on page 42,698 of the proposed rule.

Formed in 1986, the Coalition is comprised of more than sixty rural hospitals designated as Medicare rural referral centers and sole community hospitals ("SCH"). Coalition hospitals share the common goal of assuring that federal hospital payment policies take into account their unique nature and role. In furtherance of this goal, the Coalition respectfully requests that CMS (1) continue the hold-harmless protections for all SCHs, and (2) extend the proposed 6.6 percent adjustment to urban SCHs.

A. Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals

The Coalition urges CMS to reconsider its decision to terminate the hold-harmless provision for transitional corridor payments, at least with respect to SCHs. The Coalition recognizes that Congress established this protection for a limited period, and that the statutory authorization for this protection is set to expire at the end of this calendar year. Nonetheless, the need for this protection remains, and CMS has ample statutory authority to perpetuate it.

The sole community hospital program was created to maintain access to needed health services for Medicare beneficiaries in isolated communities. The SCH program ensures the

viability of hospitals that are geographically isolated and thus play a critical role in providing access to care.

Because SCHs are the sole source of hospital services in their community, Congress has long appreciated the special role of SCHs and the need to afford SCHs special recognition and protections under the Medicare program to ensure their continued viability. For example, SCHs are specially treated under Medicare's inpatient prospective payment system ("IPPS"). Whereas most hospitals are reimbursed under the IPPS rates, SCHs are paid the greater of the IPPS rates or a cost-based payment. In setting SCHs apart, Congress recognized that these hospitals provide critically necessary services to Medicare beneficiaries in areas where access to other providers is limited or unavailable, and expressed a desire to buttress these hospitals with special payment status to ensure their viability.

For the same reasons that Congress extended special treatment to these hospitals under the IPPS, Congress extended special treatment to SCHs under the OPPS. Specifically, section 411 of the Medicare Modernization Act provided that SCHs would be held harmless under the OPPS by paying SCHs under either the OPPS rate or a cost-based reimbursement formula, whichever is greater for the individual hospital.

Regrettably, cost considerations led Congress to limit the duration of this protection, and the congressional mandate that CMS provide this protection is set to expire. Nonetheless, the need for this protection remains. An examination of available CMS data indicates that approximately 339 of the 540 SCHs qualify for hold-harmless payments, and that the average hold-harmless payment adjustment is 21.04 percent above the OPPS payment the hospital would otherwise receive. While some SCHs will benefit by CMS's proposed 6.6 percent OPPS adjustment, this amount will not begin to compensate most SCHs for the hold-harmless protections that they will lose if CMS allows this protection to lapse.

Moreover, while helpful, the proposed 6.6 percent adjustment is not adequately addressing the needs of SCHs. Congress provided similar hold-harmless protection under the IPPS, because it recognized that SCHs should not operate with extensive Medicare reimbursement deficits. The across-the-board payment adjustment does not attempt to assist hospitals that operate with extensive Medicare reimbursement deficits. Rather, it attempts to put rural SCHs on a level playing field with urban hospitals with respect to Medicare payments. While this may be a laudable goal, it does nothing to ensure the viability of SCHs, and to ensure access to hospital services in isolated communities. By its nature, some SCHs that have costs lower than OPPS payments will benefit by the across-the-board payment adjustment, while those that have costs that exceed payments will continue to experience payment deficits. These deficits may compromise the services these hospitals are able to offer to their communities, and the very viability of these hospitals.

For these reasons, the Coalition urges CMS to extend the hold-harmless protections for SCHs. The Coalition believes that CMS has the statutory authority to do so notwithstanding the expiration date in section 411. Section 1833(t)(2)(E) gives the Secretary broad discretion to adjust payments to hospitals of any type to ensure equity. Specifically, section 1833(t)(2)(E) provides, "the Secretary shall establish...outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary

to ensure equitable payments, such as adjustments for certain classes of hospitals" (emphasis added). This authority permits the Secretary to apply whatever adjustment he deems necessary, and to any class or category of provider he deems appropriate. Hold-harmless payments for SCHs would be an "adjustment" for a "class of hospitals", and therefore authorized by this grant of discretion.

B. Rural Hospital Adjustment

The Coalition applauds CMS for the work that it did to study cost differentials between urban hospitals and rural SCHs, and for its proposal to adjust payments for rural SCHs. The Coalition certainly encourages CMS to finalize this proposal. However, the Coalition asks CMS to clarify whether it intends to make this adjustment available beyond 2006, and whether it intends to reestablish the adjustment amount on an annual basis.

Additionally, the Coalition urges CMS to likewise evaluate SCHs as a class, and to adjust payments for all SCHs without distinguishing based on geographic location. Urban and rural SCHs fulfill identical functions. Congress established the SCH program to provide special protections to hospitals that by reason of factors such as isolated location, weather conditions, travel conditions, and absence of other like hospitals, are the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. SCHs play a critical role in our healthcare infrastructure. Without these hospitals, residents of the isolated communities they serve would have to travel great distances, in many cases hundreds of miles, to reach a full-service hospital. Hospitals with SCH status fulfill this function regardless of whether they are classified by Medicare as being located in a rural or urban area.

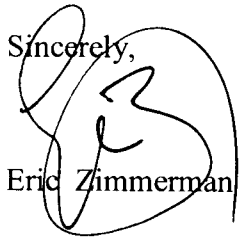
Moreover, urban and rural hospitals both must establish that they are the sole source of care in the community they serve. In fact, the qualification criteria are more stringent for urban hospitals, because they have only one way in which to qualify for SCH status (an urban hospital may qualify for SCH status only if it is more than 35 miles from another like hospital, whereas a rural hospital can demonstrate its isolation and qualify for SCH status in several ways). Although the area an SCH may serve may be considered urban, it nonetheless may be isolated and otherwise lacking hospital services.

CMS likewise has the statutory authority to adjust OPPS payments for urban SCHs, too. Section 1833(t)(13) instructs the Secretary to conduct a study to determine if rural hospital outpatient costs exceed urban hospital outpatient costs, and authorizes the Secretary to provide an appropriate adjustment to *rural* hospitals by January 1, 2006, if rural hospital costs are determined to be greater than urban hospital costs. Although this section does not expressly authorize the Secretary to likewise adjust payments for urban SCHs, the Secretary has the authority to do so under section 1833(t)(2)(E), which gives the Secretary broad discretion to adjust payments to hospitals of any type to ensure equity. This authority permits the Secretary to apply whatever adjustment he deems necessary, and to any class or category of provider he deems appropriate.

* * * * *

Please contact me at 202.756.8148 or ezimmerman@mwe.com if you have any questions concerning these comments.

Sincerely,



Eric Zimmerman

PPTA
Plasma Protein Therapeutics Association

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Congressional attached

September 16, 2005
Reference No.: HPSC05052

BBP Payment DBR

Ahmed Kane Hunter

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule concerning the 2005 hospital outpatient prospective payment system ("OPPS") rates that was published in the Federal Register on July 25, 2005 ("Proposed Rule").[1] As an association deeply committed to the health and safety of the patients we serve, our comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("Plasma Therapies") in the hospital outpatient setting.

PPTA is the association that represents the commercial producers of plasma therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the plasma therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins ("IVIG") used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors (A1PI) used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

We write primarily to address our concerns about the significant payment rate reduction that has been proposed for IVIG. IVIG is the only effective treatment for primary immunodeficiency disease and also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States licensed IVIG products are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial

[1] 70 Fed. Reg. 42674.

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PPTA Offices in Washington · Annapolis · Brussels · Tokyo

infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals affected by diseases or conditions treated with IVIG depend on this life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious and potentially life threatening complications.

The drastic payment reductions proposed by CMS (51% reduction for lyophilized and a 30% decrease for liquid) will impede access to IVIG by Medicare beneficiaries currently treated in hospital outpatient departments. This is particularly detrimental because, at the start of this year when physician offices began to be paid for IVIG based on the same methodology CMS proposes for hospital outpatient payments, patients migrated from physician offices to hospital outpatient departments to receive their IVIG treatments because of inadequate reimbursement. We are very concerned that, as reimbursement is decreased in the hospital outpatient department there will be little or no other alternatives for Medicare beneficiaries who are dependent upon IVIG.

We urge CMS, in finalizing the 2006 OPPS rates, to take steps to ensure that hospitals are paid sufficiently for IVIG so that it remains a viable setting for the provision of IVIG. CMS could do this by establishing an add-on payment to the rate for IVIG that captures the true acquisition, direct and indirect handling costs associated with IVIG that are above and beyond the rate CMS otherwise determines for the product and pharmacy overhead. Although we believe this add-on would be the most appropriate mechanism to preserve patient access, the agency could instead implement a dampening mechanism, as it has done in the past, to ensure that access to IVIG in hospital outpatient departments is maintained. In addition, the agency should consider establishing unique Healthcare Common Procedure Coding System ("HCPCS") codes for each brand of IVIG so that the average sales price ("ASP") for each IVIG is based on information submitted for that product such that if CMS were to set OPPS rates using ASP, the rates would be more accurate. Lastly with regard to IVIG, CMS should clarify that IVIG is a biologic response modifier for purposes of paying hospitals for administering the product.

In addition to concern about the adequacy of reimbursement at ASP+6%+2% to ensure access to IVIG, we are also concerned about sustaining access to alpha-1 proteinase inhibitors (A1PI). PPTA urges CMS to work closely with patient and provider groups to ensure that patients have access to all three alpha-1 proteinase inhibitors. As CMS is aware, there are circumstances in which a weighted ASP does not reflect the current hospital acquisition cost. This occurs most frequently in the case of HCPCS codes that contain multiple therapies. We are hopeful that CMS will continue to recognize the importance of providing access to all therapies so physicians may provide beneficiaries the most medically appropriate treatment available.

ENSURING ADEQUATE PAYMENT RATE FOR IVIG ["Non-Pass-Throughs"]

As mentioned above, PPTA is most concerned about the significant reduction in the payment rate for IVIG and the likelihood that finalizing the proposed rates would diminish access to IVIG in the hospital outpatient department. Currently, the OPPS payment rate for one gram of IVIG, in either the liquid or the lyophilized form, is $80.68. Under the Proposed Rule, the payment for the liquid form would drop to $57.26 and the payment for the lyophilized form would drop to $39.46. With access to IVIG in physician offices curtailed in 2005, a similar result in the hospital outpatient department could leave patients who depend on IVIG with no alternative. CMS must act to avoid such a result. Below we provide some options to ensure that beneficiaries have access to IVIG in hospital outpatient departments.

A. Add on

We urge CMS, in finalizing the 2006 OPPS rates, to take steps to ensure that hospitals are paid sufficiently for IVIG so that it remains a viable setting for the provision of IVIG. CMS could do this by establishing an add-on payment to the rate for IVIG that captures the acquisition, direct and indirect handling costs associated with IVIG that are above and beyond the rate CMS otherwise determines for the product and pharmacy overhead.

PPTA recognizes that the issue of reimbursement for IVIG in all settings has been a complex one. As a result, we are working with the Lewin Group to help clarify the marketplace so that the agency can set appropriate payment policies that will preserve patient access to IVIG in all settings. This study, however, is a significant undertaking, and one that will take some time. We will be pleased to provide this information to CMS upon completion of the project for future ratesetting. PPTA urges CMS to adopt an interim measure to ensure that hospitals are adequately reimbursed for IVIG and we offer the preliminary findings of a pilot study from the Lewin Group as the basis for an interim add-on payment to the ASP+6%+2% payment rate (see attachment).

- The current physician payment rate is not adequate to ensure patient access to IVIG services in physician practices. The last line of defense for many Medicare IVIG patients at this time is the hospital outpatient setting, and hospitals are struggling to ensure they can meet that demand at current payment rates.

- The January 1, 2005 change in Part B reimbursement has resulted in a migration of IVIG patients from physician offices to hospitals.

- Some respondents noted that the change in payment methodology for Part B drugs seems not only to have resulted in physicians transferring their patients to

other settings, but, in some instances, keeping their IVIG allocation for use with the non-Medicare patient population.

Appendix A indicates that the cost of goods already exceeds the ASP for our median estimate. This is not sustainable.

B. Need for a Dampening Mechanism for IVIG

This Proposed Rule is reminiscent of the OPPS rulemaking for the 2003 payment rates in that CMS is again implementing a major shift in how it pays for drugs and biologicals such as IVIG under OPPS. For that year, the payment methodology was shifting as the result of most products having their pass-through status end and being paid under the median cost methodology. For 2006, there again is a major shift in the payment methodology – from the transitional mechanism put in place by Congress for 2004 and 2005 to a permanent mechanism that CMS has proposed to be based on ASP. Just as the agency took steps in the 2003 rulemaking to avoid adversely impacting access to drugs through the use of a dampening mechanism, the same concerns about access to IVIG justify the use of such a mechanism in 2006.

In response to the last major shift in the OPPS payment methodology for drugs, CMS said that it was "concerned that our payments not compromise access of Medicare beneficiaries to high quality services" and thus adopted a few changes "designed to better ensure that the payment rates we establish in this rule are as accurate and reasonable as possible." [2] Responding to information provided to it raising significant concerns about the payment reductions for blood and blood products (including antihemophilia clotting factor), the agency applied a "dampening" mechanism to these products which ensured that payment rates would not fall by more than 15% from 2002 to 2003. [3]

The current situation is remarkably similar to three years ago. The OPPS rates for IVIG are facing precipitous reductions and the concerns about access are as significant as they were for blood clotting factors at that time. PPTA was appreciative of the agency's recognition of the need to avoid payment rate reductions that would adversely impact access and we urge CMS to take similar action to ensure access to IVIG in 2006. We, therefore, ask CMS to employ a mechanism that would ensure that payment rates for IVIG do not fall by more than 15% in 2006 from the current rates.

Alternatively, CMS could apply a modified version of the "dampening provision" proposed in the 2003 rulemaking process as many products lost their pass-through status and were paid under the median cost methodology to lessen the impact of

[2] 67 Fed. Reg. 66718, 66749 (Nov. 1, 2002).
[3] 67 Fed. Reg. at 66750.

dramatic reductions in payment rates for IVIG. CMS stated that the dampening option "mitigate[s] the potential for underpayment" in cases where "costs show significant fluctuations."[4]

Like 2003, the shift in payment methodology proposed for 2006 would drastically reduce the payment rate for IVIG. For example, at present the payment rate for IVIG in the hospital outpatient setting is $80.68. The proposed 2006 OPPS payment rate for liquid IVIG is $56.71 and $39.46 for lyophilized. Even accounting for the 2% for pharmacy overhead costs, the proposed rates represent reductions of 30% and 51% respectively. It is unreasonable to expect hospital outpatient clinics to be able to adjust to such a drastic reduction in payment without significant consequences. These consequences are most likely to take the form of clinics deciding not to acquire, stock and administer IVIG therapy. This will be tantamount to denying access to care for the patients who rely on IVIG and may well lead to adverse health consequences among this vulnerable population.

Consequently, we recommend that CMS adopt a dampening provision that will limit the reduction in payment rate for IVIG to 15% during the first year of the new payment methodology. A maximum 15% payment reduction for IVIG will force cost efficiencies among hospital outpatient clinics but will not likely lead to a compromise in patient care. This could be achieved by setting the add-on payment at a level equal to the dollar amount necessary to achieve a payment reduction of no more than 15%. In this way CMS can keep payment rates more in line with actual hospital acquisition costs and continue to use the market-based ASP as a reimbursement benchmark in a manner that will optimize patient care and healthcare costs.

C. Expanded HCPCS Codes for IVIG Products

To the extent that CMS finalizes its proposal to pay for all separately payable drugs under OPPS based on ASP information, PPTA believes that the agency could enhance the representativeness of the payment rate for each IVIG product by establishing a unique HCPCS code for each brand. That would allow the agency to determine an ASP for each brand based on its own ASP information, yielding rates that are pertinent to each brand and thus may enhance access to IVIG products.

The following brands of intravenous immune globulin are now available in the United States market: Polygam® SD, Panglobulin® NF, Gammar® P I.V., Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, Iveegam® EN, and Gammagard® Liquid. Establishing a separate HCPCS codes for each brand is appropriate because there are important clinical differences among them, such as:

- Some brands contain no sugars, which is beneficial for diabetics;

[4] 68 Fed. Reg. 4798, 48003 (Aug. 12, 2003).

- Some brands have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some brands contain sucrose, which can create a higher risk of renal failure;
- Some brands contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and
- Some brands have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

Because of these differences, there are clinical reasons why physicians prescribe a specific IVIG brand. CMS' coding and payment for these brands also should recognize these differences, which could be done be establishing separate HCPCS codes for each brand. That, in turn, would allow CMS to determine separate and more representative payments for each brand.

D. IVIG Is a Biologic Response Modifier

In the Proposed Rule, CMS indicates that it anticipates using new Current Procedural Terminology ("CPT") codes for drug administration services under OPPS in 2006. These new codes correspond to G codes that CMS currently uses to pay physicians for drug administration services under the physician fee schedule[5]. PPTA does not object to the use of these new codes to pay for the administration of drugs under OPPS, but urges CMS to clarify that IVIG is considered a "biologic response modifier" for purposes of the code to be billed for administering the product.

Under these new codes, chemotherapy administration codes apply to parenteral administration of biologic response modifiers, according to the language of the code. As a result, any product that is a "biologic response modifier" should be billed under such codes. IVIG is such a product. According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to "immunotherapy," which is defined as "Treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."[6] IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Thus, there can be no doubt that IVIG is a biologic response modifier, and CMS must state clearly in the final rule that hospitals should bill for administering the product using the CPT codes applicable to biologic response modifiers.

Access to all therapies

[5] 70 Fed. Reg. at 42737
[6] *See* http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy.

PPTA remains concerned that ASP plus 6% may not be adequate to protect patient access to all plasma derived and recombinant analog therapies. We are especially concerned about access to alpha-1 proteinase inhibitors (J0256). We therefore ask CMS to implement the APC Panel's recommendation to evaluate all drugs and biologicals during the transition to reimbursement at ASP plus 6% to monitor "precipitous" drops in reimbursement rates that could harm access to these therapies. PPTA also requests that CMS monitor access to A1PI and blood clotting factors in the hospital outpatient settings and adjust administration rates as needed to protect access to care.

PPTA appreciates CMS' recognition of the need for additional payment to compensate hospitals for the service and handling costs associated with furnishing advanced therapies.[7] Studies cited in a recent Medicare Payment Advisory Commission (MedPAC) report found that these costs are significant, ranging from 25 to 33 percent of pharmacy-related direct expenses.[8] We commend CMS for proposing an additional payment for these costs, but we are concerned that the proposed 2 percent of ASP for separately paid drugs and biologicals might not be sufficient reimbursement for these important services. As recommended by the APC Panel, CMS should reconsider this proposal, accept and consider industry data regarding these costs, and develop rates that more accurately reflect pharmacy overhead costs.

PPTA also commends CMS for its efforts to develop a more refined method for reimbursing hospitals for pharmacy service costs in the future. CMS proposes to instruct hospitals to report charges by using new C-codes for pharmacy handling services.[9] We generally support this proposal as a potential mechanism for reimbursing hospitals, and we agree that CMS needs to begin collecting data on pharmacy service costs in 2006 so it can set accurate rates in the future. As MedPAC reported, however, most hospitals do not currently charge for their handling costs, and no systematic, consensus based approach exists for measuring these costs.[10] Developing such an approach will require dedication of considerable time and effort. We are concerned that hospitals will not undertake the time-consuming process of setting appropriate charges for these services and accurately billing the new C-codes unless doing so is tied to reimbursement. To ensure that these codes are used effectively, CMS should delay implementation of the codes until January 1, 2007, as recommended by the APC Panel, and continue to refine the codes and develop instructions for their use.

CONCLUSION

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[7] Id. at 42730.
[8] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.
[9] 70 Fed. Reg. at 42730.
[10] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 143.

PPTA
Plasma Protein Therapeutics Association

PPTA appreciates the opportunity to comment on the Proposed Rule. We are deeply concerned about the impact the Proposed Rule could have on the lives of patients who depend upon IVIG, as the proposed reimbursement decrease is drastic. Moreover, given that the hospital outpatient department has taken on increasing importance as a site of service for the administration of IVIG due to migration of patients previously treated in physician offices, such cuts may leave patients with no other options for receiving IVIG. PPTA believes that an add-on payment to the rate for IVIG based on the blood clotting factor model would ensure continued access to IVIG in hospital outpatient departments in 2006. Alternatively, the agency could implement a dampening mechanism to ensure that payment rates for IVIG do not drop by more that 15%. In addition, CMS should establish a unique HCPCS code for each brand of IVIG to yield rates that are pertinent to each brand. CMS should also clarify that IVIG is a biologic response modifier so that hospitals will be paid appropriately for administering the product to beneficiaries.

Attached is a letter from Congressman Jerry Weller (R-IL) who eloquently expresses his concern for beneficiary access to IVIG in a September 14, 2005 letter to Administrator McClellan. We hope you will also consider the Congressman's viewpoints in your rulemaking process. PPTA looks forward to working with CMS to ensure continued access to IVIG in the hospital outpatient and other settings. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer

Julie Birkofer
Executive Director, North America

APPENDIX A: IVIG Cost Calculations Based on Hospital Reporting

COSTS PER GRAM (COSTS/Average dose)										vs. 6%	vs. 2%
POWDER	Handling	Materials	Pharmacist	Tech	Transp.	Overhead	TOTAL/g	TOTAL/Dose	Cost of Goods (Allocated Price)	Cost of Goods as % over ASP	Handling as % ASP
LOW	$ -	$ 0.06	$ 0.07	$ 0.04	$ 0.01	28%	**$ 0.23**	**$ 19.97**	$ 39.80	**8.9%**	**0.6%**
MED	$ 0.45	$ 0.08	$ 0.08	$ 0.12	$ 0.03	33%	**$ 1.01**	**$ 86.55**	$ 48.38	**32.4%**	**2.8%**
HIGH	$ 0.70	$ 0.29	$ 0.10	$ 0.53	$ 0.18	38%	**$ 2.48**	**$ 211.83**	$ 50.00	**36.8%**	**6.8%**
LIQUID	Handling	Materials	Pharmacist	Tech	Transp.	Overhead	TOTAL/g	TOTAL/Dose			
LOW	$ -	$ 0.06	$ 0.07	$ 0.03	$ 0.01	28%	**$ 0.22**	**$ 10.76**	$ 50.50	**-5%**	**0.4%**
MED	$ 0.45	$ 0.08	$ 0.08	$ 0.05	$ 0.03	33%	**$ 0.92**	**$ 46.16**	$ 54.50	**2.8%**	**1.7%**
HIGH	$ 0.70	$ 0.29	$ 0.10	$ 0.22	$ 0.18	38%	**$ 2.06**	**$ 102.86**	$ 58.00	**9.4%**	**3.9%**

ASP Based on CMS Proposed Rule

			8% of ASP	ASP+8%
Non-Lyophilized (liquid)	$ 53.02	gram	$ 4.24	$ 57.26
Lyophilized (powder)	$ 36.54	gram	$ 2.92	$ 39.46

Assumptions

Average dose = **85.36** grams

Overhead is applied to all costs excluding Cost of Good

TOTAL is merely the sum of per gram costs plus overhead

TOTAL/Dose is the total costs times average dose

Overhead costs were not reportable by hospitals in time for this study, therefore an industry range was used

***All calculations are based on a limited sample of hospitals and should be considered only as a very broad indicator of the costs present in the IVIG market

JERRY WELLER
11TH DISTRICT, ILLINOIS

DEPUTY MAJORITY WHIP

COMMITTEE ON
WAYS AND MEANS

SUBCOMMITTEE ON TRADE

SUBCOMMITTEE ON
SELECT REVENUE MEASURES

UNITED STATES
HOUSE OF REPRESENTATIVES

HOUSE POLICY COMMITTEE

COMMITTEE ON
INTERNATIONAL RELATIONS

SUBCOMMITTEE ON
WESTERN HEMISPHERE
(VICE CHAIR)

SUBCOMMITTEE ON
INTERNATIONAL TERRORISM &
NONPROLIFERATION

September 14, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

I would like to raise the issue of Intravenous Immune Globulin (IVIG) and its reimbursement under the Medicare Hospital Outpatient Prospective Payment System. After being informed of patient access difficulties with IVIG under the Average Sales Price (ASP) plus 6% methodology currently utilized under Medicare Part B, I am concerned that Medicare would consider the same methodology without an additional add-on payment for IVIG within the hospital outpatient system.

IVIG is a plasma therapy that is the only effective treatment of primary immune deficiency, a rare and orphan designated condition. It also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases, and certain other rare conditions. As a therapy for rare diseases, patient access is crucial. The present reimbursement environment under Medicare Part B is resulting in certain cases where health care providers can no longer purchase IVIG as the cost of the therapy is exceeding its reimbursement. This has resulted in patients being shifted to the hospital outpatient site of service for treatment. With Medicare now proposing to implement the same model for the outpatient site of service, plus an additional 2% of ASP for hospital pharmacy overhead, I am concerned that a similar situation may develop in hospital outpatient care thus leaving those reliant on IVIG without recourse.

The Medicare Physician Advisory Committee reported that in the hospital outpatient system, hospital overhead is estimated to be 25-33% of ASP, as this site typically requires greater pharmacy preparation time than do those provided to inpatients. Further, CMS' own Ambulatory Payment Code Advisory Committee recommended that CMS reconsider the 2% add-on for pharmacy overhead costs in addition to reviewing industry data regarding such costs. I would request that you to take this into account, specifically as it relates to IVIG, when CMS formulates the final rule for the 2006 Medicare Hospital Outpatient Prospective Payment System.

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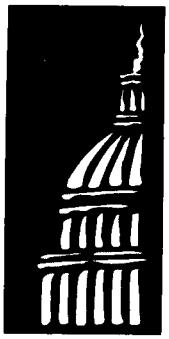
Patient groups, infusion suites, group purchasing organizations, distributors, manufacturers of IVIG and the American Academy of Allergy, Asthma and Immunology have all united in their request that CMS adjust reimbursement for IVIG from what was originally proposed in 2006. Specifically, this coalition has requested that CMS consider an add-on payment or furnishing fee be considered in addition to the proposed reimbursement. This add-on payment will recognize the unique attributes associated with preparing and administering IVIG. As an alternative, CMS may also consider implementing a dampening mechanism as they implemented in 2003 rulemaking. This dampening effect, which required a reduction in reimbursement of no greater than 15%, would serve to blunt the substantial blow that hospital outpatient facilities would incur in 2006. More importantly, this dampening effect would still provide adequate reimbursement for hospital outpatient facilities purchasing IVIG, thus ensuring continued patient access.

I would ask that you consider all options when considering reimbursement for IVIG. Lack of access to this life saving product in the physician's office due to reimbursement has been problematic and the situation will grow worse if the same is allowed to happen in the hospital outpatient setting. Your attention to this situation as CMS prepares its final rule for 2006 will be greatly appreciated.

Thank you for your consideration and I look forward to discussing this matter.

Sincerely,

Jerry Weller
Member of Congress



ACNP

AMERICAN COLLEGE OF NURSE PRACTITIONERS

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S/T Kushnirova
Nurse Phy Pract Collins

September 16, 2005

Centers for Medicare and Medicaid Services
CMS-1501-P
Post Office Box 8016
Baltimore, MD 21244-8018

File Code: CMS-1501-P

Dear Dr. McClellan:

On behalf of the American College of Nurse Practitioners (ACNP), I want to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Notice of Proposed Rulemaking regarding the Hospital Outpatient Prospective Payment System for 2006[1] as it pertains to Physician Oversight of Mid-Level Practitioners in Critical Access Hospitals (CAHs).

ACNP is a national, nonprofit, professional organization dedicated to advancing access to appropriate, prevention-based health care provided by nurse practitioners (NPs). We provide legislative, regulatory, and public affairs representation for over 30,000 nurse practitioners.

Nurse practitioners are registered nurses who are prepared, through advanced education and clinical training, to provide a wide range of preventive and acute health care services to individuals of all ages. Today, NPs complete graduate-level education preparation that leads to a master's degree. NPs take health histories and provide complete physical examinations; diagnose and treat many common acute and chronic problems; interpret laboratory results and X-rays; prescribe and manage medications and other therapies; provide health instruction and supportive counseling with an emphasis on prevention of illness and health maintenance; and refer patients to other health professionals as needed. NPs are authorized to practice across the nation and have prescriptive privileges, of varying degrees, in 50 states. The most recent Health Resources and Services Administration Sample Survey report (2000) shows 102,829 nurse practitioners in the United States, an increase of more than 44 percent over 1996 data. The actual number of nurse practitioners in 2004 was estimated to be at least 115,000.

[1] 70 Fed. Reg. 42674 (July 25, 2005).

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Section XVI. Physician Oversight of Mid-Level Practitioners in Critical Access Hospitals

ACNP appreciates CMS' acknowledgement that nonphysician providers are providing the highest level of patient care with relative autonomy, as supported by the June 2002 MedPAC Report to Congress and the January 5, 2000 edition of The Journal of the American Medical Association, among others. Nurse practitioners provide critical health care services to patients in rural and medically underserved areas, providing a medical home to patients who might not otherwise have access to primary and preventative health care services.

Given the growing clinical independence of nurse practitioners, we question the proposal being offered by CMS to add an additional federal requirement – and administrative burden of chart and patient record reviews – to physicians that work under collaborative agreements with nurse practitioners in certain states. NPs practicing under these types of agreements do so under the authority of state licensure laws, as well as medical licensure boards in those states.

According to *The Pearson Report: A National Overview of Nurse Practitioner Legislation and Healthcare Issues*,[2] twenty-one states have no requirement for any physician involvement in the diagnosis and treatment aspects of a nurse practitioner's clinical practice. Six states require physician involvement but do not require specific written documentation of that relationship. And twenty-four states require some level of physician involvement, which must be documented in writing. It should be clear that the involvement requirement for a physician's relationship with a nurse practitioner varies from state to state and encompasses the full spectrum of collaboration, supervision, authorization and/or delegation to direction of activities.

In my state of Delaware for example, nurse practitioners practice independently without written guidelines or protocols. Nurse practitioners maintain clinical practices and operate with relative autonomy, though we are required by state licensure law to maintain a collaborative agreement with a physician – in the event hospitalization, consultation or referral is required. In our state there is no requirement for physician record or chart review. We are required to submit a written copy of a collaborative agreement with the state's Joint Practice Committee.

Of the six states cited by The Pearson Report as requiring physician involvement in the practice of nurse practitioners, only one provides that physicians be willing to participate in some level of chart or patient record review. ACNP fully supports giving states the authority to decide whether to require physicians to review and sign medical records of CAH outpatient records, based on the governing laws and licensure standards in place in

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[2] The Pearson Report, Linda Pearson, DNSc, MSN, APRN, BC, A National Overview of Nurse Practitioner Legislation and Healthcare Issues, January 2005, Vol 9, No 1, The American Journal for Nurse Practitioners, page 13.

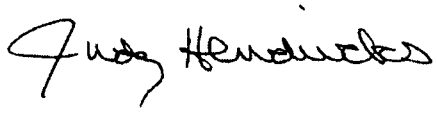
those states, however does not support the imposition of new federal requirement that goes beyond existing state licensure laws.

It is unclear to ACNP how CMS will determine the states that do not have independent practice laws, since states do not generally refer to these types of agreements using terms such as "autonomous" or "independent." More and more states are describing these agreements as collaborative in nature. In fact, states described in all three reporting categories contained in The Pearson Report use the word "collaborative" as descriptors for their requirements. States have already made the determination, as part of the licensure process, for how nurse practitioners may practice in that state.

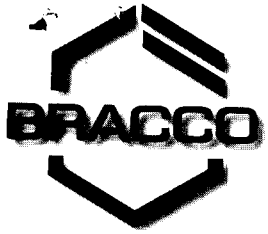
While it is our hope that CMS will not adopt any new requirement for patient record reviews, if the Agency does proceed, we hope it can be done in the narrowest possible manner. States where nurse practitioners enjoy some form of collaborative agreement with physicians and have no state law requiring record review should not be saddled with a new administrative burden.

Thank you once again for the opportunity to provide our input on the proposed regulation. If we can provide further clarification to our written comments, please feel free to contact Amy Demske, ACNP's Washington Representative at (202) 857-6484.

Sincerely,



Judy Hendricks, MS, ANP
President
American College of Nurse Practitioners



THE IMAGE OF INNOVATION

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September 16, 2005

Bretz
Richter

By Hand

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–1501-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1501-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Administrator McClellan:

On behalf of Bracco Diagnostics Inc., I am writing to formally comment for the record, on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates." See 70 Fed. Reg. 42,674 (July 25, 2005) (the "Proposed Rule"). Bracco appreciates and welcomes this opportunity to comment on an important aspect of the Proposed Rule, and looks forward to working with CMS to ensure that the Rule is implemented in a manner that reflects not just our concerns, but also the implications of patient safety.

I. BACKGROUND

Bracco Diagnostics ("Bracco") is a member of the Bracco Group, one of the world's leading diagnostic imaging companies. Bracco is responsible for the development and marketing of innovative diagnostic imaging contrast agents and products, including Isovue®, Multihance®, and ProHance®, which represent a sizable share of the U.S. diagnostic pharmaceuticals market. These and other contrast media products are critical for performing diagnostic imaging, an important, first line procedure for diagnosing and treating many severe and life-threatening conditions.

Bracco Diagnostics Inc.
107 College Road East - Princeton, New Jersey 08540 USA - Telephone: (609) 514-2200 / (800) 631-5245 - Facsimile: (609) 514-2424 www.bdi.bracco.com

II. THE PROPOSED RULE

In the Proposed Rule, CMS announced that it intends to require hospitals to report the use of low osmolar contrast media (LOCM) in an outpatient setting by using Q-codes. See id. at 42,727. These same codes were implemented earlier this year in the physician office setting. CMS also proposes to pay for these codes in the same manner as other separately payable drugs – i.e., on the basis of average sales price (ASP). As described in these comments, Bracco is concerned about the proposed use of these new codes and the corresponding ASP payment methodology.

As published in the Proposed Rule, and as Bracco has noted in other communications with the agency, the reimbursement rates for the contrast media codes increases as the iodine or active material concentration decreases. See id. at 42,962. In other words, lower level concentrations of contrast media are associated with higher payment rates. We reproduce below the payment and dosing information published in the Proposed Rule:

HCPCS	Description	Dose	Payment
Q9945	LOCM < = 149 mg/mL	1 mL	$0.51
Q9946	LOCM 150 – 199 mg/mL	1 mL	$2.00
Q9947	LOCM 200 – 249 mg/mL	1 mL	$0.78
Q9948	LOCM 250 – 299 mg/mL	1 mL	$0.66
Q9949	LOCM 300 – 349 mg/mL	1 mL	$0.41
Q9950	LOCM 350 – 399 mg/mL	1 mL	$0.27
Q9951	LOCM >= 400 mg/mL	1mL	$0.20

While we recognize that manufacturers report the ASPs that are used to set these reimbursement rates, we believe that the coding tiers adopted by CMS do not appropriately collect the various contrast media products, the result of which is a payment scheme that is inconsistent with the Medicare Program's interests. In addition, we have observed the payment rates change significantly in the second quarter reporting posting.

A. The Proposed Reimbursement Methodology for Low Osmolar Contrast Media May Inappropriately Affect Hospital Decision-making

In particular, Bracco is concerned that such a payment scheme might be a perverse incentive for hospitals to use a lower concentration LOCM in diagnostic imaging procedures in order to qualify for higher reimbursement rates. Specifically, hospitals may obtain a higher reimbursement for the same results by using a greater volume of a low concentration media than would be needed if a higher concentration media were used. For example, for a patient requiring a pelvis computerized tomography scan with a need to deliver a total of 44.4 grams of iodine at a flow rate of 1.2 grams of iodine per second for the procedure, the payment differentials are as follows:

- To achieve a dosage requirement of 44.4 grams of iodine using a 250 mg I/mL concentration of contrast media, 178 mL of volume must be administered, resulting in reimbursement of $117.48.

- To achieve the same 44.4 grams of iodine dosage using a 370 mg I/mL concentration of contrast media, only 120 mL of volume is needed, resulting in reimbursement of $32.40.

Thus, CMS will be paying 3.6 times more ($117.48 versus $32.40) for the 250 mg/mL concentration than for the 370 mg/mL concentration. Further, not only will Medicare be paying substantially more, but it will be doing so for therapies that are not as effective as the lower cost higher concentration alternatives. Consequently, we believe the agency should review whether an alternative reimbursement mechanism would be more appropriate for LOCM.

B. The Proposed Reimbursement Methodology May Negatively Affect Patient Safety

More importantly, the dramatic increase in the reimbursement rate for Q9946 and concurrent large decreases in the reimbursement rates for Q9947 through Q9951 could motivate clinically unnecessary – and potentially dangerous – switches in contrast media selections. For example, as noted above, 120 mL of contrast media is necessary to achieve a dosage of 44.4 grams of iodine if a 370 mg/ml concentration if used. By comparison, to achieve the same dosage of iodine with a 250 mg/ml concentration, 178 ml of contrast media is needed. This could expose patients to a greater possibility of contrast-induced nephropathy and other volume-related adverse events, as well as a higher risk of extravasation. While we do not believe most hospitals will ignore these risks in order to maximize their reimbursement, implementing a reimbursement methodology that discourages these behaviors should help reduce the prospect of such payment-based decisions.

III. RECOMMENDATION

As described above, the Proposed Rule raises important policy issues that could significantly affect reimbursement and patient safety from the administration of LOCM. To address the aforementioned issues, we urge CMS to revise its Q-code classifications of contrast media as follows:

Proposed HCPCS Matrix

HCPCS	Description	Dose	Payment
Q 9945	LOCM < = 199 mg/mL	1 mL	$
Q 9946	LOCM 200 – 249 mg/mL	1 mL	$
Q 9947	LOCM 250 – 299 mg/mL	1 mL	$
Q 9948	LOCM 300 – 399 mg/mL	1 mL	$
Q 9949	LOCM >=400 mg/mL	1 mL	$

This represents compression of the concentration levels of < = 149 mg/mL through 199 mg/mL, since only 0.5% of all imaging procedures utilize concentrations at these levels. The concentration levels of 300 mg/mL through 400 mg/mL are also compressed since approximately 88% of all procedures utilize concentrations at these levels. In both cases, payment can be adjusted based on a blended ASP derived from the preexisting categories.

IV. CONCLUSION

We appreciate the opportunity to comment on this important issue raised by CMS's Proposed Rule. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,

Robert L. Aromando, Jr.
Vice President of Marketing

Hey Gastere Sept 8, 2005 137

Dear Mr McClellan,

I am writing in response to a notice in the July Federal Register regarding reduced rates paid to hospitals for Cryosurgery.

I had Cryo surgery in April of 2005 and thank God both of the medical. It was minimally invasive and only required an overnight hospital stay. I have felt zero recurrence and have required no follow up procedures.

I would like to see more access to this procedure, more hospitals offering it and urge Medicare to adjust the proposed payment rate upward to cover hospital costs for Cryo surgery. This procedure is truly a miracle in the treatment of prostate cancer.

Sincerely,
Vincent Bugeja
Vincent Bugeja
22460 Maiden Rd
St Clair Shores MI 48081
586 354-6421

138

McDermott
Will & Emery

Boston Brussels Chicago Düsseldorf London Los Angeles Miami Milan
Munich New York Orange County Rome San Diego Silicon Valley Washington, D.C.

Eric Zimmerman
Attorney at Law
ezimmerman@mwe.com
202.756.8148

Ritter
Kushnirova

September 15, 2005

5/I
Rural Agd

BY HAND DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1501–P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, CMS–1501–P, 70 *Fed. Reg.* 42,674 *et seq.* (July 25, 2005).

Dear Sir or Madam:

Please accept these comments regarding proposed changes to the hospital outpatient prospective payment system ("OPPS") and calendar year 2006 payment rates, and specifically the **Rural Hospital Adjustment** discussed beginning on page 42,698. These comments are being submitted on behalf of a coalition of hospitals with sole community hospital ("SCH") status that are also all located in urban areas. These hospitals recommend that the Centers for Medicare & Medicaid Services ("CMS") adjust OPPS payments for all SCHs regardless of geographic location.

A. Policy Justifications

For the following reasons, CMS should adjust payments for all sole community hospitals as a class without distinguishing based on geographic location.

- **SCH status is indicative of higher unit costs.**

We asked The Moran Company ("TMC") to perform the same regression analysis conducted by CMS replacing the "Rural SCH" dummy variable with an SCH variable that reported all hospitals with SCH status to examine whether SCH status, rather than geographic location, was indicative of higher costs. TMC found that CMS's statistical models were fundamentally unchanged when adjusted to examine all SCHs, rather than just rural SCHs. The implication of this finding is that the SCH status, and not rural/urban classification, is statistically associated with higher unit costs.

The following two tables prepared by TMC show CMS's results examining rural SCHs, and TMC's results examining all SCHs.

Table 1: Regression Results for Unit Outpatient Costs, Explanatory Model

Variable	CMS results			TMC Results		
	Regression coefficient	t Value	p Value	Regression coefficient	t Value	p Value
Intercept	4.89444	124.70	<.0001	4.89148	124.58	<.0001
Wage Index	0.64022	17.85	<.0001	0.64105	17.89	<.0001
Service-Mix Index	0.75798	58.56	<.0001	0.75842	58.61	<.0001
Outpatient Volume	-0.06538	-14.43	<.0001	-0.06558	-14.47	<.0001
Beds	0.04533	6.26	<.0001	0.04601	6.35	<.0001
Rural SCH	0.05668	3.42	0.0006			
SCH				0.05292	3.33	0.0009
All Other Rural	0.00415	0.29	.7715			
All Rural				0.00580	0.42	0.6760
Children's Hospital	0.06475	1.33	0.1835	0.06509	1.34	0.1810
Psychiatric Hospital	-0.44345	-15.11	<.0001	-0.44255	-15.08	<.0001
Long-Term Care Hospital	-0.08644	-2.73	0.0063	-0.08556	-2.71	0.0068
Rehabilitation Hospital	-0.25234	-7.83	<.0001	-0.25142	-7.81	<.0001
Cancer Hospital	0.30957	3.46	0.0005	0.31136	3.48	0.0005
R2	0.5295			0.5297		

Source: CMS Results from Table 6, 70 *Fed. Reg.* at 42,701; TMC results based on TMC calculations.

Table 2: Regression Results for Unit Outpatient Costs, Payment Model

Variable	CMS results			TMC Results		
	Regression coefficient	t Value	p Value	Regression coefficient	t Value	p Value
Intercept	4.24474	768.57	<.0001	4.24428	763.14	<.0001
Rural SCH	0.06354	3.94	<.0001			
SCH				0.06112	3.95	<.0001
R2 – as calculated by TMC	.0035			.0036		

Source: CMS Results from Table 6, 70 *Fed. Reg.* at 42,701; TMC results based on TMC calculations.

TMC also examined the cost characteristics of urban SCHs alone, and found that the parameter estimate for urban SCHs (0.5503) is close to the parameter estimate for rural SCHs (0.5857), which implies that rural SCH status and urban SCH status have very similar impacts on costs. In light of these similar impacts, TMC concludes that using a single variable to represent SCH status would be appropriate and produce accurate results.

The entire TMC report and analysis is enclosed. Additional detail concerning TMC's findings can be obtained from TMC or through me.

- **Urban and rural SCHs fulfill identical functions.**

Congress established the sole community hospital program to provide special protections to hospitals that by reason of factors such as isolated location, weather conditions, travel conditions,

and absence of other like hospitals, are the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. SCHs play a critical role in our healthcare infrastructure. Without these hospitals, residents of the isolated communities they serve would have to travel great distances, in many cases hundreds of miles, to reach a full-service hospital. Hospitals with SCH status fulfill this function regardless of whether they are classified by Medicare as being located in a rural or urban area.

In fact, urban SCHs fulfill the core SCH function perhaps even more so than rural SCHs. Critical Access Hospitals ("CAH") are not considered "like hospitals" for purposes of qualifying for SCH status. As a result, a hospital can have a CAH located nearby and still qualify for SCH status. However, only rural SCHs would potentially have CAHs nearby, since CAHs cannot be designated in urban areas. As such, an urban SCH is truly the only source of hospital services within 35 miles, whereas a rural SCH may have alternative sources of hospital services within that distance.

- **Urban and rural hospitals must satisfy the same criteria to qualify for SCH status.**

Urban and rural hospitals both must establish that they are the sole source of care in the community they serve. In fact, the qualification criteria are more stringent for urban hospitals, because they have only one way in which to qualify for SCH status (an urban hospital may qualify for SCH status only if it is more than 35 miles from another like hospital, whereas a rural hospital can demonstrate its isolation and qualify for SCH status in several ways). Although the area an SCH may serve may be considered urban, it nonetheless is isolated and otherwise lacking hospital services.

- **Most of the areas served by urban SCHs are rural in character.**

In fact, most of the areas served by *urban* SCHs are actually *rural* in character despite their urban designation. In many cases, the hospital is located in very large county (*e.g.*, Matanuska-Susitna, Alaska) or a county on the extreme outskirts of a metropolitan area (*e.g.*, Bates, Missouri), and far away from the metropolitan center. Although enough residents in parts of the county that are closer to the metropolitan center commute to that area for work to qualify the entire county as urban, the area in which the hospital is located, and which the hospital serves, is unquestionably rural in character. Places like Jourdanton, Texas, Poteau, Oklahoma, Longview Washington, Farmington, New Mexico, Tooele, Utah, Butler, Missouri, and Joshua Tree, California, where urban SCHs are located, would not be characterized as urban other than by Medicare's definition of the term. In fact, most of the areas in which urban SCHs are located were considered rural prior to implementation of the new metropolitan area definitions in fiscal year 2005. As such, it is inaccurate to characterize urban SCHs as somehow serving different roles or populations than their rural counterparts.

- **Urban SCHs share more characteristics with rural SCHs than other urban hospitals.**

Urban SCHs tend to be more comparable to rural SCHs and rural hospitals in general in key characteristics than to urban hospitals. Table 3 below illustrates this likeness by looking at bed size, service mix, and wage index statistics across four categories of hospitals.

Table 3: Means for key variables by urban-rural location and SCH status

	All Rural Hospitals	All Urban Hospitals	Rural SCHs	Urban SCHs
No. of Hospitals	1,257	2,820	488	46
Beds	76.70	198	73.86	108.54
O/P Service Mix	2.4121	2.7741	2.3899	2.5114
Wage Index	0.8798	1.0214	0.8902	0.9956

Source: Results taken from Table 4, 70 *Fed. Reg.* at 42,699 and MWE calculations. Detail available from MWE.

Urban SCHs are more comparable to rural SCHs and rural hospitals than to urban hospitals in terms of bed size and service mix. Moreover, 9 urban SCHs are located in metropolitan areas with a wage index below the rural part of the state, and which therefore are eligible for the rural wage index floor.

- **Congress did not distinguish between urban and rural hospitals in the SCH qualification criteria, and intended for the special benefits available to qualifying hospitals to apply regardless of geographic location.**

Congress created the sole community hospital program to maintain access to needed health services for Medicare beneficiaries in isolated communities. In so doing, Congress did not distinguish between urban and rural hospitals. Section 1886(d)(5)(D) of the Social Security Act makes no reference to geographic status, and does not distinguish between urban and rural hospitals in the qualification criteria or the special benefits available to qualifying hospitals. Urban SCHs are eligible for and receive the same protections under the inpatient prospective payment system as rural SCHs. An isolated hospital is isolated, and needs buttressing, regardless of how Medicare classifies the surrounding geographic area.

B. Statutory Authority

CMS has the statutory authority to adjust OPPS payments for urban SCHs, too. Section 1833(t)(13) instructs the Secretary to conduct a study to determine if rural hospital outpatient costs exceed urban hospital outpatient costs, and authorizes the Secretary to provide an appropriate adjustment to *rural* hospitals by January 1, 2006, if rural hospital costs are determined to be greater than urban hospital costs. Although this section does not expressly authorize the Secretary to likewise adjust payments for urban SCHs, the Secretary has the authority to do so from elsewhere in the statute. Section 1833(t)(2)(E) gives the Secretary broad discretion to adjust payments to hospitals of any type to ensure equity. Specifically, section 1833(t)(2)(E) provides, "the Secretary shall establish...outlier adjustments under paragraph (5)

and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals" (emphasis added). This authority permits the Secretary to apply whatever adjustment he deems necessary, and to any class or category of provider he deems appropriate.

Moreover, the authority granted under section 1833(t)(2)(E) is in no way constrained by the authority conferred by section 1833(t)(13)(B). The latter merely directs the Secretary to adjust payments to *rural* hospitals, if supported by the mandated study. However, this section in now way precludes or limits likewise adjusting payments to urban SCHs, if supported by a comparable, distinct analysis.

C. Impact Analysis

Our analysis indicates that of the 534 hospitals with SCH status, only about 48 (approximately 9 percent) are located in urban areas. Moreover, our analysis indicates that applying a 6.6 percent or comparable adjustment to urban SCHs would increase payments to these hospitals by only approximately $16 million.

Of course, extending a comparable OPPS adjustment to urban SCHs would not increase program costs. Section 1833(t)(2)(E) provides that any adjustment applied by the Secretary must be done in a budget neutral manner.

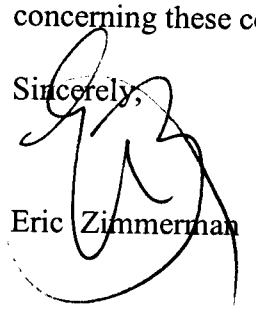
D. Recommendation

In light of the foregoing, these hospitals recommend that CMS repeat its regression analysis to confirm that SCH status, and not geographic location, is indicative of higher costs, and, if so, to appropriately adjust OPPS payments for all SCHs.

* * * * *

Please contact me at 202.756.8148 or ezimmerman@mwe.com if you have any questions concerning these comments.

Sincerely,



Eric Zimmerman

Enclosure
cc: Daniel Shostak, The Moran Company

An Examination of Outpatient Unit Costs for Sole Community Hospitals

Analysis of "Rural Hospital Adjustment" as Proposed by CMS (70 FR 42698)

Prepared For:

McDermott Will & Emery LLP

September 2005

Prepared By:

Daniel I. Shostak
Gregory J. Watson
Rose C. Chu
Marla Kugel

THE MORAN COMPANY

An Examination of Outpatient Unit Costs for Sole Community Hospitals:

Analysis of "Rural Hospital Adjustment" as Proposed by CMS (70 FR 42698)

Introduction

McDermott Will & Emery, LLP, asked The Moran Company (TMC) to explore the analysis conducted by the Centers for Medicare and Medicaid Services (CMS) on the proposed adjustment for Rural Sole Community Hospitals in the proposed Outpatient Rule. The CMS analysis is located at 70 FR 42698-42701, July 25, 2005, and would affect payments after January 1, 2006.

The results of our analysis of CMS's findings and our own modeling of CMS's data indicate that CMS's statistical models are fundamentally unchanged if the models are adjusted to examine all Sole Community Hospitals (SCH) as opposed to just rural Sole Community Hospitals.

The implication of this finding is that the SCH status, not the rural/urban designation, is statistically associated with higher unit costs.

Results

After identifying urban sole community hospitals, TMC performed similar regressions to those that CMS reported as Table 6 (70 FR 42701). The TMC models made two modifications:

1. The "Rural SCH" indicator variable was replaced with an SCH variable that reported a hospital's SCH status.
2. The "All Other Rural" indicator variable was replaced with an "All Rural" dummy variable. This was necessary because of the removal of the "Rural SCH" variable which also reported rural status.

In response to comments and questions posed during a meeting with CMS on September 9, 2005, TMC also modeled separating out urban sole community hospitals as an independent variable. To this end, TMC included an indicator variable reporting "Urban SCH status" to the CMS based models.

The CMS published results and TMC results are below.

Exhibit 1: Regression Results for Unit Outpatient Costs - Explanatory Model

Variable	CMS Results			TMC Results		
	Regression coefficient	t Value	p Value	Regression coefficient	t Value	p Value
Intercept	4.89444	124.70	<.0001	4.89148	124.58	<.0001
Wage Index	0.64022	17.85	<.0001	0.64105	17.89	<.0001
Service-Mix Index	0.75798	58.56	<.0001	0.75842	58.61	<.0001
Outpatient Volume	-0.06538	-14.43	<.0001	-0.06558	-14.47	<.0001
Beds	0.04533	6.26	<.0001	0.04601	6.35	<.0001
Rural SCH	0.05668	3.42	0.0006			
SCH				0.05292	3.33	0.0009
All Other Rural	0.00415	0.29	.7715			
All Rural				0.00580	0.42	0.6760
Children's Hospital	0.06475	1.33	0.1835	0.06509	1.34	0.1810
Psychiatric Hospital	-0.44345	-15.11	<.0001	-0.44255	-15.08	<.0001
Long-Term Care Hospital	-0.08644	-2.73	0.0063	-0.08556	-2.71	0.0068
Rehabilitation Hospital	-0.25234	-7.83	<.0001	-0.25142	-7.81	<.0001
Cancer Hospital	0.30957	3.46	0.0005	0.31136	3.48	0.0005
R^2	0.5295			0.5297		

Source: CMS Results from Table 6, 70 FR 42701
TMC results based on TMC calculations. Detail available from TMC.

Exhibit 2: Regression Results for Unit Outpatient Costs - Payment Model

Variable	CMS results			TMC Results		
	Regression coefficient	t Value	p Value	Regression coefficient	t Value	p Value
Intercept	4.24474	768.57	<.0001	4.24428	763.14	<.0001
Rural SCH	0.06354	3.94	<.0001			
SCH				0.06112	3.95	<.0001
R^2 – as calculated by TMC	0.0035			0.0036		

Source: CMS Results from Table 6, 70 FR 42701
TMC results based on TMC calculations. Detail available from TMC.

Exhibit 3: Regression Results for Unit Outpatient Costs: Separate Rural and Urban SCH Variables - Explanatory Model

Variable	CMS results			TMC Results		
	Regression coefficient	t Value	p Value	Regression coefficient	t Value	p Value
Intercept	4.89444	124.70	<.0001	4.89137	124.41	<.0001
Wage Index	0.64022	17.85	<.0001	0.64111	17.88	<.0001
Service-Mix Index	0.75798	58.56	<.0001	0.75844	58.58	<.0001
Outpatient Volume	-0.06538	-14.43	<.0001	-0.06559	-14.46	<.0001
Beds	0.04533	6.26	<.0001	0.04603	6.34	<.0001
Rural SCH	0.05668	3.42	0.0006	0.05857	3.52	0.0004
Urban SCH				0.05503	1.30	0.1928
All Other Rural	0.00415	0.29	.7715	0.00600	0.42	0.6764
Children's Hospital	0.06475	1.33	0.1835	0.06511	1.34	0.1810
Psychiatric Hospital	-0.44345	-15.11	<.0001	-0.44252	-15.07	<.0001
Long-Term Care Hospital	-0.08644	-2.73	0.0063	-0.08553	-2.71	0.0069
Rehabilitation Hospital	-0.25234	-7.83	<.0001	-0.25139	-7.80	<.0001
Cancer Hospital	0.30957	3.46	0.0005	0.31143	3.48	0.0005
R^2	0.5295			0.5296		

Source: CMS Results from Table 6, 70 FR 42701
TMC results based on TMC calculations. Detail available from TMC.

Exhibit 4: Regression Results for Unit Outpatient Costs: Separate Rural and Urban SCH Variables - Payment Model

Variable	CMS results			TMC Results		
	Regression coefficient	t Value	p Value	Regression coefficient	t Value	p Value
Intercept	4.24474	768.57	<.0001	4.24428	763.08	<.0001
Rural SCH	0.06354	3.94	<.0001	0.06401	3.96	<.0001
Urban SCH				0.03350	0.71	0.4777
R^2 – as calculated by TMC	0.0035			0.0034		

Source: CMS Results from Table 6, 70 FR 42701
TMC results based on TMC calculations. Detail available from TMC.

Discussion

Section 411 of the Medicare Modernization Act (MMA) instructed the Secretary of Health and Human Services to examine whether rural hospital outpatient costs exceed urban hospital outpatient costs. Furthermore, the Secretary is authorized to provide an appropriate adjustment to rural hospitals on January 1, 2006, if the research indicates that rural hospital costs are found to be greater than those of urban hospitals.

In the early stages of their research, CMS found that when it did not control for various factors, rural hospitals had lower costs per unit than urban hospitals (70 FR 42699). Then CMS adjusted for service-mix and wages and calculated simple averages of unit costs.

The agency's finding was that "average unit costs are nearly identical between urban and rural hospitals." With these two initial findings, CMS concluded that "a simple comparison of unit costs is insufficient because the costs faced by hospitals, whether urban or rural, will be a function of many factors." Therefore, CMS sought to build an "explanatory" regression model that took into account:

- Labor markets of hospitals,
- Mix of services provided by outpatient departments
- Volume of outpatient services
- Scale of the hospital
- Rural/urban setting of the facility
- Facility specialty

The rationale behind developing a regression model is that simple averages may not adequately describe the differences between different types of hospitals. A regression model allows controlling for other factors that are not accounted for in a simple average.

CMS's second explanatory regression model is presented in Exhibit 1 above (Table 6 found at 70 FR 42701).

CMS's first presentation of an explanatory regression model (Table 5 in the Rule) demonstrated reasonably good explanatory power with an adjusted R-square of 0.53. However, two variables in this model were not statistically significant at the $p<0.05$ level: the rural status indicator and the children's hospital indicator. Notwithstanding these borderline statistical findings, CMS explained that its model suggests that rural hospitals are approximately 2.4% more costly than urban hospitals after considering the other variables.

Based on its first explanatory regression model, CMS then estimated its first payment model that sought to isolate the difference in unit costs for rural hospitals. The payment regression model explains unit costs based solely on whether a facility was in an urban or rural location. CMS reported that rural status was statistically associated with a 3.7 percent increase in unit costs ($p=0.0012$). TMC's replication of this payment model confirmed CMS's finding. However, TMC's results on the payment regression model generated a very low R-square of 0.0035 that implied that this approach explained little of the variation in unit costs.[1]

In the next phase of their analysis, CMS set out to assess whether the observed difference in rural unit costs was uniform across rural hospitals or concentrated within certain classes of these facilities. Noting that rural SCHs and rural hospitals with fewer than 100 beds are eligible for additional payments, CMS researchers revised their model so that rural SCH hospitals, small rural hospitals and other rural hospitals could be distinguished. CMS did not publish its results using these three variables. In its second published

[1] TMC calculated the R^2 because it is not published as a part of the proposed rule.

explanatory regression model (Table 6; see Exhibit 1 above) CMS found that rural SCHs had higher costs per unit than urban hospitals after controlling for the other variables.

Most interestingly, CMS's new explanatory model indicated that "all other rural hospitals" and children's hospitals did not have a statistically significant difference in unit costs in comparison to urban hospitals.

However, CMS found that rural SCHs did have a statistically significant difference in unit costs in comparison to urban hospitals ($p=0.0006$). Replacing rural status with rural SCH status in the Payment model, CMS reports that unit costs are 6.4% higher in rural SCHs.

The Moran Company's replication of CMS's second Explanatory and Payment models confirmed CMS's report. TMC than performed an analysis flagging SCH status and rural/urban status separately (see Exhibit 1). This model indicated that it was SCH status, not rural SCH status, which was associated with higher unit costs. The TMC Payment model using SCH status generated a 6.1% increase in unit costs for SCHs (see Exhibit 2).

Conclusion

This analysis suggests the following conclusions:

CMS's work in the proposed rule focuses on the issue of rural SCH status and does not address issues relating to urban SCH providers. Our analysis suggests that urban and rural SCH providers face similar cost differentials relative to non-SCH urban providers. The reasoning for this conclusion is as follows:

1. CMS's univariate analyses indicate that rural hospital costs per unit are less than or similar to urban unit costs (see CMS Table 4 at 70 FR 42699);
2. CMS's initial explanatory multivariate analysis (Table 5) reports that the coefficient of the rural variable is not statistically significant at the generally accepted cut-off level of $p<0.05$.
3. CMS writes in the proposed rule that the evidence that outpatient services provided by rural hospital are more costly than outpatient services provided by urban hospitals is "weak." See page 42700 of the Federal Register.
4. The coefficient of the "all other rural hospitals" variable in the second Explanatory model (Table 6 and presented in Exhibit 1 above) is not statistically significant ($p=0.77$);
5. The statistically significant coefficients found in CMS's two payment regression models (Tables 5 and 6 from the proposed rule) do not provide further clarification. After comparing these two regression models, it is possible to surmise that that SCH status has its own explanatory power because the regression coefficient changes dramatically when identifying rural SCHs as opposed to all rural facilities.

Additional TMC regression modeling using CMS data implies that the SCH status of a facility, not its rural/urban designation, is statistically associated with higher unit costs for Medicare outpatient services:

1. A TMC explanatory regression model that uniquely identified SCHs and rural/urban status separately found that SCH designation is statistically significant, while the rural/urban status variable is not (See exhibit 1 above).
2. In an alternative explanatory model, we refined our model to divide SCH into type of SCH, either rural or urban. The goal here was to try and have a more detailed look at the potential effects of various factors. Our parameter estimates for rural SCH (0.5857) were very close to that for urban SCH (0.5503), which implies that rural SCH status and urban SCH status have very similar impacts on costs. Since they have similar impacts, we believe that using a single variable to represent SCH may be appropriate and produce accurate results. We recognize that the urban SCH coefficient is not statistically significant (p=0.1928), but this finding does not lead to immediately ruling out the explanatory power of this variable.
3. Finally, TMC examined models limited to SCH providers in order to explain SCH unit costs using CMS's explanatory model variables (i.e., wage index, service-mix, outpatient volume and beds) and an indicator variable reflecting rural/urban status. All factors resulted in statistically significant coefficients, except rural/urban status. The implication of this finding is that rural/urban status does not affect an SCH's unit costs.

CMS's reported findings along with TMC's results would seem to indicate that further research may be appropriate to gain a more thorough understanding of the cost differentials of different provider types.

Appendix A: Methodology

Methodology and Data Sources

Methodology replication

Prior to making any refinements on the variables used by CMS in their models, TMC replicated exactly the methodology used by CMS, using the data that CMS had released and after consulting with CMS on its approach.

Data and Urban Sole Community Hospital Identification

CMS provided a very complete and useful dataset. The CMS data used was the "Proposed 2006 OPPS Hospital-Specific Impacts" file available from CMS at: http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp.

After CMS's results were successfully replicated, the only variable that TMC added was an indicator for urban sole community hospital. Rural sole community hospitals were already identified on the CMS file. Urban sole community hospitals were identified as follows:

1. Restrict the data set to urban hospitals
2. Merge on data from the Outpatient Provider Specific Files from the PC Pricer available from http://www.cms.hhs.gov/providers/pricer/default.asp#downloads. Using the file that was effective July 2005, determine if a provider was a sole community hospital. Sole Community Hospitals were identified by having provider type code 16 or 17, per Section 50.1 of the documentation for the Outpatient Pricer, available at: http://www.cms.hhs.gov/manuals/104_claims/clm104c04.pdf
3. For those urban hospitals that did not match with the Outpatient Pricer Provider Specific Data, merge on information from the Inpatient Prospective Payment System (IPPS) impact file for FY 2006, available from: http://www.cms.hhs.gov/providers/hipps/ippspufs.asp Identify SCH designated facilities using this data.
4. From urban providers where the status was still unknown, assume that the provider is not a sole community hospital.

Refinements to models

TMC refined both CMS and TMC models by examining unit costs by logically adding or substituting indicators for sole community hospital status, urban SCHs, rural SCHs, or rural/urban status. To execute our refinements, we revised the CMS hospital specific data so that each hospital was identified as to its SCH status and its post-reclassification rural/urban status. As a result of these two changes, our "base case model" would be urban non-SCH hospitals.

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Joaquin Duato
President

ORTHO BIOTECH

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AHMED

September 16, 2005

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445–G, HHS Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan,

On behalf of Ortho Biotech Products, L.P., I am pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2005 (CMS-1501-P, Federal Register, Vol. 70, No. 141, Monday, July 25, 2005, p. 42674). Ortho Biotech Products, L.P. markets ORTHOVISC® (High Molecular Weight Hyaluronan), a product approved by the FDA on February 4, 2004 for the treatment of pain in osteoarthritis (OA) of the knee.

Ortho Biotech appreciates the considerable effort you and your staff have put into the development of the outpatient prospective payment system (OPPS) and to your commitment to ensure patient access to the full range of drugs and other treatments, with fair and equitable payment to hospitals. Our comments in this letter will focus on payment for ORTHOVISC® (High Molecular Weight Hyaluronan), a product approved by the FDA on February 4, 2004 for the treatment of pain in osteoarthritis (OA) of the knee.

PAYMENT OF ORTHOVISC® UNDER THE OPPS

We are pleased by the CMS proposal to continue pass-through status in CY 2006 for ORTHOVISC, which is reported with HCPCS code C9220 *Sodium hyaluronate per 30 mg dose, for intra-articular injection.*

However, we are very concerned that once the period of eligibility for pass-through payments expires, there will not be a code corresponding to C9220 that will be available for use. We have expressed our concerns to the CMS HCPCS Workgroup following their preliminary recommendation to deny a unique code for ORTHOVISC and to include ORTHOVISC with other viscosupplements described by HCPCS code J7317. Because the decision of the CMS HCPCS Workgroup could have an impact on OPPS payments for ORTHOVISC in the future, we feel obligated to submit as comments on this proposed rule our response to the preliminary decision of the Workgroup.

We believe that a new code is necessary and appropriate for ORTHOVISC under the established HCPCS process. Such a decision would recognize the unique characteristics of ORTHOVISC, distinguish it from other viscosupplements, allow for appropriate payment, and facilitate patient access.

ORTHOVISC was approved by the FDA on February 4, 2004 and launched in the US market on March 1, 2004. FDA approval was based on a PMA application submitted with the combined analysis of 2 large randomized controlled trials demonstrating the safety and efficacy of ORTHOVISC.

The approved package insert reads as follows:

> *"ORTHOVISC is indicated in the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics e.g. acetaminophen."*

Approved by the FDA as a device, ORTHOVISC is paid like a drug by most third-party payers, including Medicare. It is administered by intra-articular injection and covered by Medicare as "incident to a physician's services" under Medicare Part B.

Ortho Biotech submitted a HCPCS J-code application on April 1, 2004 and an application for a C-code under the Outpatient Prospective Payment System (OPPS) on May 27, 2004. The outpatient C-code was approved on November 2, 2004, resulting in a unique code as well as payment under the OPPS on a pass-through basis. After the request for a HCPCS code was denied last year, Ortho Biotech resubmitted its J code application under the new HCPCS process on December 23, 2004.

The preliminary recommendation of the HCPCS Workgroup to deny the application is inappropriate for several reasons:

- It fails to recognize ORTHOVISC's physical and clinical differences, including the number of injections to complete a course of therapy, compared to the other hyaluronic acid products.
- It likely will provide a financial incentive for the use of other viscosupplements, overshadowing physician and patient advantages, and skewing the market toward the alternative products.
- It will reduce or eliminate access to the only FDA approved 3-injection natural viscosupplement.
- It will eliminate the ability of payers, clinicians, and researchers to track utilization and clinical outcomes of alternative products though claims data.
- It is inconsistent with the previous CMS decisions that established a separate ASP rate under Part B for ORTHOVISC and created a unique C code for OPPS pass through payments.

ORTHOVISC is physically different from the hyaluronic acid products included in J7317; consequently, a course of treatment involves fewer injections. As shown in the table below, ORTHOVISC has greater viscosity, higher molecular weight, greater concentration of hyaluronan, and requires 3 or 4 injections (most typically 3) in a course of treatment compared to 5 injections for the J7317 products.

Brand Name	Generic name	Number of weekly injections per treatment course	Dose Per Injection	Viscosity (Pa-sec at 0.02 Hz)	Molecular Weight ($X10^6$ D)	Hyaluronan Concentration (µg/mL)
ORTHOVISC	High Molecular Weight Hyaluronan	3 or 4	30 mg	42	1.0 – 2.9	15
Supartz	Sodium Hyaluronate	5	25 mcg	0.3	0.62 – 1.17	10
Hyalgan	Sodium Hyaluronate	5	20 mg	<0.1	0.5 – 0.73	10

Looking solely at the number of injections per course of treatment, ORTHOVISC is similar to Synvisc, as shown in the table on page 4, but these products are different chemically. In particular, ORTHOVISC is the only "ultra pure natural hyaluronan." It also has the highest hyaluronic acid concentration of the four products.

Brand Name	Generic name	Number of weekly injections per treatment course	Dose Per Injection	Viscosity (Pa-sec at 0.02 Hz)	Molecular Weight ($X10^6$ D)	Hyaluronan Concentration (µg/mL)
ORTHOVISC	High Molecular Weight Hyaluronan	3 or 4	30 mg	42	1.0 – 2.9	15
Synvisc	Hylan G-F 20	3	16 mg	213	6 (Hylan A only) 0.5 – 0.73	8

The dose (mg per injection) for products currently included in J7317 is 20-25 mg and the dose for ORTHOVISC is 30 mg. Simply revising the code descriptor to include the larger dose would ignore the reduction in the total number of injections required for a course of therapy, and would create a serious financial disincentive to use ORTHOVISC.

The table below compares the cost of treatment of the four products over a typical course of therapy based on the proposed 2006 OPPS rates. As shown, the proposed payment of ORTHOVISC (including both the payment for the drug and payment for administering the injection) at a 3 injection regimen is significantly less than Supartz and Hyalgan at a 5 injection regimen: $990.42 vs $1203.35.

	Orthovisc (a)	**Supartz (a)**	**Hyalgan (a)**	**Synvisc (a)**
Reimbursement Per Injection	$ 200.12	$ 110.65	$ 110.65	$ 203.15
Injection Fee	$ 130.02	$ 130.02	$ 130.02	$ 130.02
Total Reimbursement	$ 330.14	$ 240.67	$ 240.67	$ 333.17
Course of Therapy (# shots)	**3**	**5**	**5**	**3**
Total Reimb - w/ injection fee	**$ 990.42**	**$1203.35**	**$1203.35**	**$ 999.51**

Savings accrue both to the Medicare trust fund and to the beneficiary in lower coinsurance payments. Notwithstanding these advantages, patients likely would not have access to the savings and to the only natural viscosupplement offering a 3-injection regimen if ORTHOVISC is bundled with Hyalgan and Supartz in code J7317. The reason for this result is that the reimbursement *per dose* for ORTHOVISC would not be sufficient to cover the acquisition cost of the product, making it highly unlikely that physicians and providers would use it. Thus, combining ORTHOVISC with the other viscosupplements would inappropriately skew the market toward use of the other products.

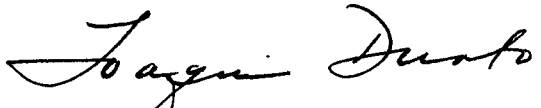
Overall Conclusions

In summary, CMS should recognize ORTHOVISC as a unique product and grant it a unique HCPCS code. Such a decision would continue the policies previously adopted by CMS when it listed ORTHOVISC as a distinct "Not Otherwise Classified (NOC) Drug" in the Average Sales Price (ASP) Medicare Part B Drug Pricing File, and when it issued a unique C code and approved ORTHOVISC to be paid as a pass-through drug.

We recommend prompt approval of our pending HCPCS application for ORTHOVISC. With an appropriate code, payment for ORTHOVISC in the future will be based on its own ASP data, not the data of other products that are administered according to a different dosing regimen.

Thank you for your consideration of our comments and recommendations. If you have any questions, please contact Cathleen Dooley at 202-589-1008 (cdooley@obius.jnj.com).

Sincerely,



Joaquin Duato
President, Ortho Biotech Products, L.P.